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DEPARTMENT OF AGRICULTURE

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■

Milk for Manufacturing Purposes and its Production and Processing

Recommended Requirements

DEPARTMENT OF AGRICULTURE

Consumer and Marketing Service

MILK FOR MANUFACTURING PURPOSES AND ITS PRODUCTION AND PROCESSING

Requirements Recommended for Adoption by State Regulatory Agencies

Statement of consideration leading to the recommended requirements. Proposed requirements for milk for manufacturing purposes and its production and processing recommended for adoption by States were published by USDA under notices in the FEDERAL REGISTER on October 25, 1969. The purpose of publishing the proposed requirements was to invite comment from State regulatory officials, the dairy industry and all other interested parties. Written data, views, or arguments in connection with the aforesaid recommendations were requested to be sent to the Hearing Clerk, U.S. Department of Agriculture, by no later than March 31, 1970.

Ninety-two letters of comment were received. The letters were reviewed and the views and opinions considered by both the Department of Health, Education, and Welfare and the U.S. Department of Agriculture. Of the 13 States commenting, a majority agreed on the following items:

(a) Use of a farm permit system rather than the proposed farm certification system.

(b) Delete the provisions for an automatic drop in the maximum bacterial level for No. 2 (acceptable) milk from individual farms from 3 million to 1 million per milliliter in 3 years after adoption by a State.

(c) Permit the continued use of the Methylene Blue test to estimate bacteria.

(d) Eliminate requirement that producers check strength of sanitizing solutions.

(e) Make requirements for farm water supplies less stringent.

(f) Require that laboratory test records on milk quality only be maintained for review by inspectors.

(g) Eliminate the recommendation that commingled milk in plant storage tanks have a bacteria count no greater than 3 million per milliliter.

The remaining 79 letters of comment were from producers, processors, and trade organizations. In general, their views supported those of the States who commented.

Careful consideration has been given to the sum and substance of each letter of comment received. The views and opinions expressed were then weighed in light of what is known of industry capability, and in light of the proportion of the industry now meeting the recommended requirements. The fact that certain States and areas are unable presently to adopt and apply these recommended requirements should not alter the significance nor the need for uniformity in the sanitary quality of manufacturing milk and its products. Instead, such areas should assess their situation and use all means necessary to systematically improve conditions step by step, to the point where the recommended requirements can be met.

Actions taken on the views and comments received are as follows: The use of either term, whether it be farm certification or farm permit, would not alter the basic concept in the recommended requirements that an established criteria must be complied with as a basis for issuance and continuance of either a permit or certification. For these reasons, the term certification was retained in the text.

Considerable apprehension was expressed in the provision to automatically reduce the maximum level of bacteria in acceptable milk from 3 million to 1 million in 3 years after adoption of the requirements. Certain areas may not have a sufficient basis by which to judge whether they could meet this drop in the specified time. Therefore, this recommended requirement is being footnoted to indicate that it will be reviewed in 3 years and, if warranted, a further extension may be granted.

The Methylene Blue test for estimating the bacterial content of milk has been demonstrated to be the least conclusive test when compared with the standard plate count, the direct microscopic count, and the resazurin reduction test. Because of its poor correlation with the other three test procedures, the Methylene Blue test will not be included as a recommended test. This is not to say that some benefit could not be derived from its use in upgrading the quality of milk. Those who are using it now will receive the full benefits of the test, to the maximum capability of the test itself. From that point on, a more definitive test procedure will be needed.

The recommendation to have producers check the strength of their sanitizing solutions has been dropped, as it is felt that proper use of sanitizing solutions can be achieved by following the directions of the manufacturer.

Dairy farm water supply requirements were changed slightly. For reasons of public health significance and for safety of the farm family and the public in general it was felt that (1) farm water supplies should at least for the present meet the State requirements, (2) that in cases where they did not meet the State requirements, such sources of farm water supplies should be upgraded to meet the requirements any time that unsatisfactory test samples were obtained, when repairs or reconstruction was necessary or when any new source was constructed. States should be able to upgrade farm water supplies so that they could comply with the construction requirements.

The only test records which are recommended to be kept for routine review by inspectors are those which pertain to sediment and bacterial tests on milk from producers, pasteurization recorder charts, and water supply and health certificates. This recognizes privacy of in-plant quality control tests and other test results, from routine surveillance.

The recommended requirement that when milk from individual farms is commingled in dairy plant storage tanks, the commingled milk shall not have a bacterial count higher than 3 million per milliliter, is being retained. The reason is that some means is necessary to determine if the milk after being received from the farm is properly refrigerated and promptly handled in a sanitary manner until processed.

In addition, editorial changes have been made in the text for the purpose of greater clarity of intent.

The purpose and intent of the recommended requirements now being published is to promote, through State adoption and enforcement, uniformity in State dairy laws and regulations as well as national uniformity in the sanitary manner in which milk for manufacturing purposes is produced and processed.

The U.S. Department of Agriculture has no legal responsibility for the enforcement of these recommended requirements within a State. This is the responsibility of each State when the requirements are adopted by a State. However, under authority granted it by the Agricultural Marketing Act of 1946, USDA will continue to assist the States in an advisory and interpretive capacity in order to promote the purpose and intent for which these requirements have been published. In addition, USDA will continue to review the progress being made toward adoption of these recommendations and if necessary will amend the recommendations to include additional time limitations for implementation.

A sample State Enabling Act to facilitate the enactment of the proposed requirements for those States not having the present authority, together with the recommended requirements, is included.

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Subpart A—Sample State Enabling Act

An act to provide for the establishment of requirements for milk for manufacturing purposes and its production and processing.

SECTION 1. It is the intent of the Act to encourage the sanitary production of good quality milk, to promote the sanitary processing of milk for manufacturing purposes, and to assure wholesome, stable, and high-quality dairy products.

SEC. 2. The [regulatory agency of the State] [1] shall administer the provisions of this Act and is hereby authorized: to establish and promulgate rules and regulations for milk for manufacturing purposes, its production, transportation, grading, use, processing, and the packaging, labeling, and storage of dairy products made therefrom; to inspect dairy farms and dairy plants; to certify dairy farms for the production and sale of milk for manufacturing purposes and to license dairy plants to handle and process milk for manufacturing purposes, in conformity with basic requirements and specifications prescribed by such rules and regulations as may be issued hereunder in effectuation of the intent hereof; to require the keeping of appropriate books and records by plants licensed hereunder; and to license qualified milk graders and bulk milk collectors.

SEC. 3. The [regulatory agency of the State] [1] may for good cause, after notice and opportunity for hearing, suspend or revoke certifications and licenses issued hereunder. Provided, that nothing in this Act shall be construed to prevent the suspension of the operation of any plant

[1] Insert name of appropriate regulatory agency, official, or department.

prior to a hearing, when such action is authorized by any applicable and valid law or regulation.

SEC. 4. Twenty-four months from and after the effective date of the rules and regulations issued pursuant to this Act, no person, firm, or corporation shall produce, sell, offer for sale, or process milk for the manufacture of human food except in accordance with the provisions of this Act and the rules and regulations issued pursuant hereto.

SEC. 5. Any person, firm, or corporation that willfully violates any provision of this Act or the rules and regulations issued pursuant hereto shall be fined not more than $_____, and each and every violation shall constitute a separate offense.

SEC. 6. This Act shall become effective _____.

Subpart B—Definitions

SECTION B 1. *Meaning of words.* Words used in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

SEC. B 2. *Terms defined.* Unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

(a) *Act.* (The State Act to provide for the establishment of Requirements for Milk for Manufacturing Purposes and Its Production and Processing.)[1]

(b) *Regulatory agency.* (Insert the name of the State agency, official, or department) is authorized by law to administer the Act.

(c) *Rules and regulations.* The provisions of Subpart B to F herein.

(d) *License.* A license issued under the Act by (the regulatory agency).

(e) *Fieldman.* A person qualified and trained in the sanitary methods of production and handling of milk as set forth herein, and generally employed by a processing or manufacturing plant for the purpose of making dairy farm surveys and doing quality control work.

(f) *Fieldman, approved.* A fieldman qualified, trained, and approved by the (regulatory agency) to perform farm inspections and raw milk grading.

(g) *Inspector.* A qualified, trained person employed by (the regulatory agency) to perform dairy farm or plant inspections and raw milk grading.

(h) *Milk grader or bulk milk collector.* A person licensed by [the regulatory agency] as described in F 2.4(b) who is qualified and trained for the grading of raw milk in accordance with the quality standards and procedures of Subparts C and F.

(i) *Producer.* The person or persons who exercise control over the production of the milk delivered to a processing plant or receiving station and those who receive payment for this product. A "new producer" is one who has only recently entered the production of milk for the market. A "transfer producer" is one who has been shipping milk to one plant and transfers his shipments to another plant.

(j) *Dairy farm or farm.* A place or premise where one or more milking cows are kept, a part or all of the milk produced thereon being delivered, sold, or offered for sale to a plant for manufacturing purposes.

(k) *Dairy plant or plant.* Any place, premise, or establishment where milk or dairy products are received or handled for processing or manufacturing and/or prepared for distribution. When "plant" is used in connection with the production, transportation, grading, or use of milk, it means any plant that handles or purchases milk for manufacturing purposes; when used in connection with requirements for plants or licensing of plants, it means only those plants that manufacture dairy products.

(l) *Milk.* The normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. The word "milk" used herein includes only milk for manufacturing purposes.

(m) *Milk for manufacturing purposes.* Milk produced for processing and manufacturing into products for human consumption but not subject to Grade A or comparable requirements.

(n) *Acceptable milk.* Milk that qualifies under sec. C 2 as to sight and odor and that is classified No. 1 or No. 2 for sediment content (sec. C 3) and No. 1 or No. 2 for bacterial estimate (sec. C 4).

(o) *Probational milk.* Milk classified No. 3 for sediment content (sec. C 3) or milk classified "Undergrade" for bacterial estimate (sec. C 4) that may be accepted by plants for specific time periods.

(p) *Reject milk.* Milk that does not qualify under sec. C 2 as to sight and odor, or that is classified No. 4 for sediment content (sec. C 3), which is rejected by the plant by the provisions of sec. C 5.

(q) *Excluded milk.* All of a producer's milk excluded from the market by the provisions of sec. C 7.

(r) *Dairy products.* Butter, cheese (natural or processed), dry whole milk, nonfat dry milk, dry buttermilk, dry whey, evaporated milk (whole or skim), condensed whole milk and condensed skim milk (plain or sweetened), and such other products, for human consumption, as may be otherwise designated.

(s) *Farm certification.* Certification by an inspector or approved fieldman that a producer's herd, milking facility and housing, milking procedure, cooling, milkhouse or milkroom, utensils and equipment and water supply have been found to meet the applicable requirements of subpart D for the production of milk to be used for manufacturing purposes.

(t) *Official methods.* Official Methods of Analysis of the Association of Official Agricultural Chemists, a publication of the Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, DC.

(u) *Standard methods.* Standard Methods for the Examination of Dairy Products, a publication of the American Public Health Association, 1790 Broadway, New York, N.Y.

(v) *3–A Sanitary Standards.* The standards for dairy equipment formulated by the 3–A Sanitary Standards Committees representing the International Association of Milk, Food and Environmental Sanitarians, the U.S. Public Health Service, and the Dairy Industry Committee. Published by the International Association of Milk, Food and Environmental Sanitarians, Box 437, Shelbyville, IN 46176.

(w) *C–I–P or cleaned-in-place.* The procedure by which sanitary pipelines or pieces of dairy equipment are mechanically cleaned in place by circulation.

(x) *Atmosphere relatively free from mold.* No more than 10 mold colonies per cubic foot of air as determined in Standard Methods.

(y) *Sanitizing treatment.* Application of any effective method or sanitizing agent to a clean surface for the destruction of pathogens and other organisms as far as is practicable. The sanitizing agents used shall comply with the Federal Food, Drug, and Cosmetic Act.

Subpart C—Quality Requirements for Milk for Manufacturing Purposes

SEC. C 1. *Basis.* The classification of raw milk for manufacturing purposes shall be based on organoleptic examination (sight and odor) and quality control tests for sediment content and bacterial estimate.

SEC. C 2. *Sight and odor.* The flavor and odor of acceptable raw milk shall be fresh and sweet. The milk shall be free from objectionable feed and other off-flavors and off-odors that would adversely affect the finished product, and it shall not show any abnormal condition (including, but not limited to, curdled, ropy, bloody, or mastitic condition), as indicated by sight or odor.

SEC. C 3. *Sediment content classification.* Milk in cans and in farm bulk tanks shall be classified for sediment content as follows: (See Table 1).

TABLE 1

SEDIMENT CONTENT[1]

Sediment-content classification	Milk in cans (off-the-bottom method, 1¼-inch diameter disc)	Milk in farm bulk tanks (mixed sample, 0.40-inch diameter disc)
No. 1 (acceptable)	Not to exceed 0.50 mg.	Not to exceed 0.50 mg. equivalent.
No. 2 (acceptable)	Not to exceed 1.50 mg.	Not to exceed 1.50 mg. equivalent.
No. 3 (probational)	Not to exceed 2.50 mg.	Not to exceed 2.50 mg. equivalent.
No. 4 (reject)	Over 2.50 mg.	Over 2.50 mg. equivalent.

[1] Insert title and code sections of State Enabling Act.

[1] Sediment content based on comparison with applicable charts of Sediment Standards prepared by the U.S Department of Agriculture. (7 CFR 58.2728 through 58.2731)

(a) *Method of testing.* Methods for determining sediment content of milk shall be those described in the latest edition of Standard Methods. For the testing of milk in cans, the off-the-bottom method shall be used. For testing bulk milk, a mixed 1-pint sample shall be tested. Sediment content shall be based on comparison with official USDA Sediment Standards. (7 CFR 58.2728 through 58.2731)

(b) *Frequency of tests.* At least once each month, at irregular intervals, the milk from each producer shall be tested as follows:

(1) *Milk in cans.* One or more cans of milk selected at random from each producer.

(2) *Milk in farm bulk tanks.* A sample shall be taken from each farm bulk tank.

(c) *Acceptance or rejection of milk.* If the sediment disc is classified as No. 1, No. 2, or No. 3, the producer's milk may be accepted. If the sediment disc is classified No. 4 the milk shall be rejected: *Provided,* That if the shipment of milk is commingled with other milk in a transport tank the next shipment shall not be accepted until its quality has been determined at the farm before being picked up; however, if the person making the test is unable to get to the farm before the next shipment it may be accepted but no further shipments shall be accepted unless the milk meets the requirements of No. 3 or better. In the case of milk classified as No. 3 or No. 4, if in cans, all cans shall be tested. Producers of No. 3 or No. 4 milk (cans or bulk) shall be notified immediately and shall be furnished applicable sediment discs and the next shipment shall be tested.

(d) *Retests.* (1) On test of the next shipment (if in cans, all cans shall be tested) milk classified as No. 1, No. 2, or No. 3, may be accepted, but No. 4 milk shall be rejected. Retests of bulk milk classified as No. 4 shall be made at the farm before pickup. The producers of No. 3 or No. 4 milk shall be notified immediately, furnished applicable sediment discs and the next shipment tested.

This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for not to exceed 10 calendar days. If at the end of this time all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2) it shall be excluded from market.

SEC. C 4. *Bacterial estimate classification.* Milk shall be classified for bacterial estimate as follows by one of the listed methods: (See Table 2).

TABLE 2

Bacterial estimate classification	Direct microscopic clump count or standard plate count	Resazurin reduction time to Munsell color standard 5 P 7/4 [2]
No. 1 can (acceptable) bulk	Not over 500,000 per ml	Not less than 2¼ hours.
	do	Not less than 3¼ hours.
No. 2 can (acceptable) bulk	Not over 3,000,000 per ml	Not less than 1½ hours.
	do	Not less than 2½ hours.
No. 2 [1] can (acceptable) bulk	Not over 1,000,000 per ml	Not less than 2 hours.
	do	Not less than 3 hours.
Undergrade can (probation—bulk al 4 weeks).	Over 3,000,000 per ml	Less than 1½ hours.
	do	Less than 2½ hours.
Undergrade [1] can (probation—bulk al 4 weeks).	Over 1,000,000 per ml	Less than 2 hours.
	do	Less than 3 hours.

[1] Effective 3 years after adoption: *Provided,* That this standard will be reviewed at that time and, if warranted a further extension may be granted.
[2] For enforcement purposes this test must be read at the times shown in the table.

(a) *Method of testing.* Methods for determining the bacterial estimate of milk shall be those described in the latest edition of Standard Methods for the Examination of Dairy Products. However, in reporting the results, the test shall be read at the times indicated in the table.

(b) *Frequency of tests.* At least once a month at irregular intervals, a mixed sample of each producer's milk shall be tested.

(c) *Acceptance of milk.* If the sample of milk is classified as No. 1 or No. 2, the producer's milk may be accepted without qualification. If the sample is classified as "Undergrade" (probational) the producer's milk may be accepted for a temporary period of 4 weeks. The producer of "Undergrade" milk shall be notified immediately.

(d) *Retests.* Additional samples shall be tested and classified at least weekly and the producer notified immediately of the results. This procedure of testing at least weekly and accepting "Undergrade" milk may be continued for a time period not exceeding 4 weeks. If at the end of this time the producer's milk does not meet the acceptable bacterial estimate requirements (No. 1 or No. 2), it shall be excluded from market.

SEC. C 5. *Rejected milk.* A plant shall reject specific milk from a producer if it fails to meet the requirements for sight and odor (sec. C 2.), or if it is classified No. 4 for sediment content, or if it fails to meet the provisions of (sec. C 11.).

SEC. C 6. All reject milk shall be identified with a reject tag and colored with harmless food coloring.

SEC. C 7. *Excluded milk.* A plant shall not accept milk from a producer for use in products:

(a) If a new producer's milk does not meet the requirements for acceptable milk (sec. C 3. and C 4.) or;

(b) If the milk has been in a probational (No. 3) sediment content classification for more than 10 calendar days (sec. C 3.); or

(c) If the milk has been classified "Undergrade" for bacterial estimate for more than 4 successive weeks (sec. C 4.).

SEC. C 8. *Quality testing of milk from producers*—(a) *New producers.* An examination shall be made on the first shipment of milk from producers shipping milk to a plant for the first time or after a period of nonshipment. The milk shall meet the requirements for "acceptable milk" (sec. C 3. and C 4.). Thereafter, the milk shall be tested in accordance with the procedure established for regular shippers.

(b) *Transfer producers.* (1) When a producer discontinues milk delivery at one plant and begins delivery to a different plant for any reason, the new buyer shall not accept the first delivery until he has requested from the previous buyer and received a copy of the record of the producer's milk quality covering the preceding 90 days and a statement of the farm certification status and date of certification, if any. The previous buyer shall furnish the new buyer with such information within 24 hours after receipt of a written request unless the records have been destroyed by means over which he has no control: *Provided,* That the new buyer may accept a producer's milk after making the request for the record by telephone and obtaining assurance from the previous buyer that the producer's milk may be accepted; the new buyer shall then make a written request to the old buyer for the producer's record.

(2) If the new buyer requests and fails to receive the quality record from the previous buyer, he shall report such fact to [the regulatory agency] and shall cause a farm inspection to be made promptly to confirm or establish certification of the transfer producer's farm.

(3) In lieu of the quality record from the previous buyer the producer may furnish the new buyer with a copy of the milk quality tests received with each remittance, monthly or semimonthly, for the preceding 90-day period.

(4) The new buyer shall examine and classify each transfer producer's first shipment of milk and shall subsequently examine shipments in accordance with the provisions of sections C 3. and C 4.

SEC. C 9. *Record of tests.* Accurate records, listing the results of quality tests of each producer, shall be kept on file at the receiving plant where performed and shall be available for examination by the regulatory agency.

SEC. C 10. *Field service.* A representative of the plant should arrange to promptly visit each producer shipping milk which does not meet the requirements for acceptable milk, for the purpose of inspecting the equipment, utensils, and facilities at the farm and to offer constructive assistance for improvement in the quality of the milk. A representative of the plant should visit each producer as often as practicable to assist in and encourage the production of high quality milk.

SEC. C 11. *Abnormal milk*—(a) *Mastitic milk.* (1) After (*date*) required laboratory examination for the presence of unwholesome mammary secretions—whether of an inflammatory, infectious, physiological, or environmental origin—shall be made on all raw milk samples at least four times in each 6 months' period. Samples shall be analyzed at an

official State laboratory or at a laboratory approved by the State regulatory agency.

(2) After (*date*) when a herd milk sample exceeds any of the following screening test results:

(i) California Mastitis Test—Weak Positive (CMT1+).
(ii) Catalase Test—30% oxygen.
(iii) Modified Whiteside Test—Positive (1+).
(iv) Wisconsin Mastitis Test—WMT value of 21 mm.

a somatic cell count using the Direct Microscopic Clump Count Method or equivalent, or the Electronic Method shall be made on that sample and the results of the somatic cell direct count shall be the official result.

(3) Whenever the somatic cell count indicates the presence of 1,500,000 or more somatic cells per ml., the following procedures shall be applied:

(i) A notice shall be sent to the producer warning him of the excessive somatic cell count.

(ii) Whenever two of the last four consecutive somatic cell counts exceed 1,500,000 cells per ml. the regulatory authority shall send a written notice thereof to the producer. This notice shall be in effect so long as two of the last four consecutive samples exceed 1,500,000 cells per ml. In addition to the written notice an inspection shall be made of the farm facility by the regulatory authority.

(4) A third milk sample shall be taken after a lapse of 3 days and within 14 days of the inspection required under (2) above. If this sample also indicates a high somatic cell count, the regulatory authority shall proceed with its responsibility to suspend the producers' certification for repeated noncompliance with the provisions of section C 11(a).

(b) *Antibiotics.* At least four times in 6 months, at irregular intervals, a separate or commingled sample of each producer's milk shall be tested for antibiotic residues. When a producer's milk shows a positive test he shall be immediately cut off from all markets. He shall not be reinstated until a subsequent test of the producer's milk is negative.

(c) *Radionuclides.* Composite milk samples should be tested for biologically significant radionuclides from selected areas in each State at a frequency which the regulatory agency determines to be adequate to protect the consumer.

(d) *Pesticides.* Composite milk samples should be tested for pesticides from selected areas in each State at a frequency which the regulatory agency determines to be adequate to protect the consumer.

Subpart D—Farm Requirements for Milk for Manufacturing

SEC. D 1. *Health of herd*—(a) *General health.* All animals in the herd shall be maintained in a healthy condition, and shall be properly fed and kept.

(b) *Tuberculin test.* The herd shall be located in an area within the State which meets the requirements of a modified accredited area in which not more than one-half of 1 percent of the cattle have been found to be infected with tuberculosis as determined by the provisions of the "Uniform Methods and Rules" for establishing and maintaining Tuberculosis-Free Herds of Cattle, and Modified Accredited Areas which are approved by the Animal Disease Eradication Division, Agricultural Research Service, U.S. Department of Agriculture. If the herd is not located in such an area, it shall be tested annually under the jurisdiction of the aforesaid program. All additions to the herd shall be from an area or from herds meeting these same requirements.

(c) *Brucellosis test.* The herd shall be located in an area within the State in which the percentage of cattle affected with brucellosis does not exceed 1 percent and the percentage of herds in which brucellosis is present does not exceed 5 percent, in accordance with provisions of the "Uniform Methods and Rules" for establishing and maintaining Certified Brucellosis-Free Herds of Cattle, Modified Certified Brucellosis Areas and Certified Brucellosis-Free Areas which are approved by the Animal Disease Eradication Division, Agricultural Research Service, U.S. Department of Agriculture. If the area in which the herd is located does not meet these requirements, the herd shall be blood-tested annually or milk-ring-tested semiannually. All additions to the herd shall be from an area or from herds meeting these same requirements. Within 3 years after the effective date of these rules and regulations all milk offered for sale for manufacturing purposes shall be from herds meeting the requirements for the eradication of brucellosis in accordance with the above Uniform Methods and Rules.

(d) *Abnormal milk.* Milk from cows known to be infected with mastitis or milk containing residues of antibiotics or other drugs, or milk containing pesticides or other chemical residues in excess of the established limits shall not be sold or offered for sale for human food. The milk shall be disposed of as the regulatory agency may direct.

SEC. D 2. *Milking facility and housing.* (a) A milking barn or milking parlor of adequate size and arrangement shall be provided to permit normal sanitary milking operations. It shall be well lighted and ventilated, and the floors and gutters in the milking area shall be constructed of concrete or other impervious material. The facility shall be kept clean, the manure removed daily and stored to prevent access of cows to accumulation thereof; and no swine or fowl shall be permitted in any part of the milking area.

(b) If milk is exposed during straining or transferring in the milking areas it shall be protected from falling particles from areas above milk facility.

(c) The yard or loafing area shall be of ample size to prevent overcrowding, shall be drained to prevent forming of standing water pools, insofar as practicable, and shall be kept clean.

SEC. D 3. *Milking procedure.* (a) The udders and flanks of all milking cows shall be kept clean. The udders and teats shall be washed or wiped immediately before milking with a clean, damp cloth or paper towel moistened with a sanitizing solution and wiped dry, or by any other sanitary method.

(b) The milker's outer clothing shall be clean and his hands clean and dry. No person with an infected cut or open sores on their hands or arms shall milk cows, or handle milk or milk containers, utensils or equipment.

(c) Cows which secrete abnormal milk shall be milked last or with separate equipment. This milk shall be excluded from the supply as required in section D 1. (d).

(d) Milk stools, surcingles and anti-kickers shall be kept clean and properly stored. Dusty operations should not be conducted immediately before or during milking. Strong flavored feeds should only be fed after milking.

SEC. D 4. *Cooling.* (a) Milk in cans shall be cooled immediately after milking (to 50° F. or lower)[1] unless delivered to the plant within 2 hours after milking. The cooler, tank, or refrigerated unit shall be kept clean.

(b) Milk in farm bulk tanks shall be cooled to 40° F. or lower within 2 hours after milking and maintained at 50° F. or lower until transferred to the transport tank.

SEC. D 5. *Milkhouse or milkroom.* (a) A milkhouse or milkroom conveniently located and properly constructed, lighted, and ventilated shall be provided for handling and cooling milk and for washing, handling, and storing the utensils and equipment. Other products shall not be handled in the milkroom which would be likely to contaminate milk, or otherwise create a public health hazard.

(b) It shall be equipped with wash and rinse vat, utensil rack, milk cooling facilities and have an adequate supply of hot water available for cleaning milking equipment. If a part of the barn or other building, it shall be partitioned, screened, and sealed to prevent the entrance of dust, flies, or other contamination. A milking parlor used strictly as a milking facility in combination with a milkhouse or milkroom, when properly equipped, arranged and maintained, need not be partitioned. Concentrates and feed, if stored in the building, shall be kept in a tightly covered box or bin. The floor of the building shall be of concrete or other impervious material and graded to provide proper drainage. The walls and ceilings shall be constructed of smooth easily cleaned material. All outside doors shall open outward and be self-closing, unless they are provided with tight-fitting screen doors that open outward or unless other effective means are provided to prevent the entrance of flies.

(c) If a farm bulk tank is used, it shall be properly located in the milkhouse or milkroom for access to all areas for cleaning and servicing. It shall not be located over a floor drain or under a ventilator.

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[1] Until 3 years after adoption, the temperature requirement for milk placed in cans will be 60° F.

(d) A small platform or slab constructed of concrete or other impervious material shall be provided outside the milkhouse, properly centered under a suitable port opening in the wall for milkhouse connections. The opening shall be fitted with a tight, self-closing door. The truck approach to the milkhouse or milkroom shall be properly graded and surfaced to prevent mud or pooling of water at point of loading.

(e) The milkhouse or milkroom and appurtenances shall be kept clean and free of trash, animals, and fowl. Pesticides shall not be stored in this room and when used shall be used in accordance with label instructions so as to prevent contamination of the milk.

SEC. D 6. *Utensils and equipment.* (a) Utensils, milk cans, milking machines (including pipeline systems), and other equipment used in the handling of milk shall be maintained in good condition, shall be free from rust, open seams, milkstone, or any unsantiary condition, and shall be washed, rinsed, and drained after each milking, stored in suitable facilities, and sanitized immediately before use with at least 50 p.p.m. chlorine solution or its equivalent. New or replacement can lids shall be umbrella type. All new utensils and equipment shall comply with applicable 3–A Sanitary Standards.

(b) Farm bulk tanks shall meet 3–A Sanitary Standards for construction at the time of installation and shall be installed in accordance with regulations of the regulatory agency.

(c) Single service articles shall be properly stored and shall not be reused.

SEC. D 7. *Water supply.* The dairy farm water supply shall be properly located, protected, and operated, and shall be easily accessible, ample, and of safe, sanitary quality for the cleaning of dairy utensils and equipment. The water supply shall come from a source which is approved by the State regulatory authority; or from a spring, dug well, driven well, bored well, or drilled well, the water from which complies with the standards of the State regulatory authority. A source that does not conform with the construction requirements of the State regulatory authority, but is tested annually by an approved laboratory and found to be safe and of sanitary quality shall be satisfactory: *Provided,* That after adoption of this regulation any new sources of water supply or any farm water supply requiring repairs or reconstruction or any source from which tested samples have been found unsatisfactory shall meet the construction requirements of the State regulatory authority.

SEC. D 8. *Sewage disposal.* House, milkhouse or milkroom and toilet wastes shall be disposed of in a manner that will not pollute the soil surface, contaminate any water supply, or be exposed to insects.

SEC. D 9. *Qualifications for farm certification.* Farm certification requires satisfactory compliance with the requirements in Subpart D.

Subpart E—Requirements for Licensed Dairy Plants

SEC. E 1. *General requirements*—E 1.1 *Premises.* (a) The premises shall be kept in a clean and orderly condition, and shall be free from strong or foul odors, smoke, or excessive air pollution. Construction and maintenance of driveways and adjacent plant traffic areas shall be of concrete, asphalt, or similar material to keep dust and mud to a minimum.

(b) Surroundings: The adjacent surroundings shall be free from refuse, rubbish, and waste materials to prevent harborage of rodents, insects, and other vermin.

(c) Drainage: A suitable drainage system shall be provided which will allow rapid drainage of all water from plant buildings and driveways, including surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard.

E 1.2 *Buildings.* The building or buildings shall be of sound construction and shall be kept in good repair to prevent the entrance or harboring of rodents, birds, insects, vermin, dogs, and cats. All service pipe openings through outside walls shall be effectively sealed around the opening or provided with tight metal collars.

(a) *Outside doors, windows, openings, etc.* All openings to the outer air including doors, windows, skylights, and transoms shall be effectively protected or screened against the entrance of flies and other insects, rodents, birds, dust, and dirt. All outside doors opening into processing rooms shall be in good condition and fit properly. All hinged, outside screen doors shall open outward. All doors and windows shall be kept clean and in good repair. Outside conveyor openings and other special-type outside openings shall be effectively protected to prevent the entrance of flies and rodents, by the use of doors, screens, flaps, fans, or tunnels. Outside openings for sanitary pipelines shall be covered when not in use. On new construction, window sills should be slanted downward at a 45° angle.

(b) *Walls, ceilings, partitions, and posts.* The walls, ceilings, partitions, and posts of rooms in which milk or dairy products are processed, manufactured, handled, packaged, or stored (except dry storage of packaged finished products and supplies) or in which utensils are washed and stored, shall be smoothly finished with a suitable material of light color, which is substantially impervious to moisture and kept clean. They shall b refinished as often as necessary to maintain a neat, clean surface.

(c) *Floors.* (1) The floors of all rooms in which milk or dairy products are processed, manufactured, packaged, or stored or in which utensils are washed shall be constructed of tile properly laid with impervious joint material, concrete, or other equally impervious material. The floors shall be smooth, kept in good repair, graded so that there will be no pools of standing water or milk products after flushing, and all openings to the drains shall be equipped with traps properly constructed and kept in good repair. On new construction bell-type traps shall not be used. The plumbing shall be so installed as to prevent the backup of sewage into the drain lines and to the floor of the plant.

(2) Sound, smooth wood floors which can be kept clean, may be used in rooms where new containers and supplies and certain packaged finished products are stored.

(d) *Lighting and ventilation.* (1) Light shall be ample, natural or artificial, or both, of good quality and well distributed. All rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least 30 foot-candles of light intensity on all working surfaces and at least 50 foot-candles of light intensity in areas where dairy products are graded or examined for condition and quality. In all other rooms there shall be provided at least 5 foot-candles of light intensity when measured at a distance of 30 inches from the floor. Where contamination of product by broken glass is possible, light bulbs, fluorescent tubes, fixtures, skylight, or other glass suspended over the product shall be protected against breakage.

(2) There shall be adequate heating, ventilation, or air conditioning for all rooms and compartments to permit maintenance of sanitary conditions. Exhaust or inlet fans, vents, hoods, or temperature and humidity control facilities shall be provided where and when needed, to minimize or eliminate undesirable room temperatuers, objectionable odors, moisture condensation, or mold. Inlet fans should be provided with an adequate air filtering device to eliminate dirt and dust from the incoming air. Ventilation systems shall be cleaned periodically as needed and maintained in good repair. Exhaust outlets shall be screened or provided with self-closing louvers to prevent the entrance of insects when not in use.

(e) *Rooms and compartments.* Rooms and compartments in which any raw material, packaging, ingredient supplies, or dairy products are handled, manufactured, packaged, or stored shall be so designed, constructed, and maintained as to assure desirable room temperatures and clean and orderly operating conditions free from objectionable odors and vapors. Enclosed bulk milk receiving rooms when present shall be separated from the processing rooms by a partition. Rooms for receiving can milk shall be separated from the processing rooms by a partition (partial or complete) by suitable arrangement of equipment or by allowing enough distance between receiving and processing operations to avoid possible contamination of milk or dairy products during manufacturing and handling. Processing

rooms shall be kept free from equipment and materials not regularly used.

(1) *Coolers and freezers.* Coolers and freezers where dairy products are stored shall be clean, reasonably dry and maintained at the proper uniform temperature and humidty to adequately protect the product, and minimize the growth of mold. Adequate circulation of air shall be maintained at all times. They shall be free from rodents, insects, and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for collecting and disposing of condensate.

(2) *Supply room.* The supply rooms used for the storing of packaging materials, containers, and miscellaneous ingredients shall be kept clean, dry, orderly, free from insects, rodents, and mold and maintained in good repair. Such items stored therein shall be adequately protected from dust, dirt, or other extraneous matter and so arranged on racks, shelves, or pallets to permit access to the supplies and cleaning and inspection of the room. Insecticides, rodenticides, cleaning compounds, and other nonfood products shall be properly labeled and segregated, and stored in a separate room or cabinet away from milk, dairy products, ingredients, or packaging supplies.

(3) *Boiler and tool rooms.* The boiler and tool rooms shall be separated from other rooms where milk and dairy products are processed, manufactured, packaged, handled, or stored. Such rooms shall be kept orderly and reasonably free from dust and dirt.

(4) *Toilet and dressing rooms.* Adequate toilet and dressing room facilities shall be conveniently located.

(i) Toilet rooms shall not open directly into any room in which milk or dairy products are processed, manufactured, packaged, or stored; doors shall be self-closing; ventilation shall be provided by mechanical means or screened openings to the outer air; fixtures shall be kept clean and in good repair.

(ii) All employees shall be furnished with a locker or other suitable facility and the lockers and dressing rooms shall be kept clean and orderly. Adequate hand-washing facilities shall be provided and curable, legible signs shall be posted conspicuously in each toilet or dressing room directing employees to wash their hands before returning to work.

(5) *Laboratory.* Consistent with the size and type of plant and the volume of dairy products manufactured, an adequately equipped laboratory shall be maintained and properly staffed with qualified and trained personnel for quality control and analytical testing. A central laboratory serving more than one plant may be acceptable if conveniently located to the dairy plants and if samples and results can be transmitted without undue delay.

(6) *Starter facilities.* Adequate sanitary facilities shall be provided for the handling of starter cultures.

E 1.3 *Facilities*—(a) *Water supply.* (1) There shall be an ample supply of both hot and cold water of safe and sanitary quality, with adequate facilities for its proper distribution throughout the plant, and protection against contamination and pollution. Water from other facilities, when officially approved, may be used for boiler feed water and condenser water provided that such waterlines are completely separated from the waterlines carrying the sanitary water supply, and the equipment is so constructed and controlled as to preclude contamination of product contact surfaces. There is no cross connection between the safe water supply and any unsafe or questionable water supply, or any other source of pollution through which contamination of the safe water supply is possible. Bacteriological examination shall be made of the sanitary water supply at least twice a year, or as often as necessary to determine purity and suitability for use in manufacturing dairy products. Such tests shall be made by the State regulatory agency except for supplies that are regularly tested for purity and bacteriological quality, and approved by the appropriate regulatory officer. The results of all water tests shall be kept on file at the plant for which the test was performed.

(2) The location, construction and operation of any well shall comply with regulations of the appropriate agency.

(b) *Drinking water facilities.* Drinking water facilities of a sanitary type shall be provided in the plant and shall be conveniently located.

(c) *Hand-washing facilities.* Convenient hand-washing facilities shall be provided, including hot and cold running water, soap or other detergents, and sanitary single-service towels or air dryers. Such accommodations shall be located in or adjacent to toilet and dressing rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products. Vats for washing equipment or utensils shall not be used as hand-washing facilities. Self-closing metal or plastic containers shall be provided for used towels and other wastes.

(d) *Steam.* Steam shall be supplied in sufficient volume and pressure for satisfactory operation of each applicable piece of equipment. Culinary steam used in direct contact with milk or dairy products shall be free from harmful substances or extraneous material and only nontoxic boiler compounds shall be used, or a secondary steam generator shall be used in which soft water is converted to steam and no boiler compounds are used. Steam traps, strainers, and condensate traps shall be used wherever applicable to insure a satisfactory and safe steam supply. Culinary steam shall comply with the recommended practices for "Producing Culinary Steam for Processing Milk and Milk Products" as published by the National Association of Dairy Equipment Manufacturers, Washington, D.C., April 1963 or latest revision thereof.

(e) *Air under pressure.* The method for supplying air under pressure which comes in contact with milk or dairy products or any product contact surface shall comply with the 3–A Accepted Practices for Supplying Air Under Pressure. The air used at the point of application shall be free from volatile substances, volatiles which may impart any flavor or odor to the products, and extraneous or harmful substances.

(f) *Disposal of wastes.* Dairy wastes shall be properly disposed of from the plant and premises. The sewer system shall have sufficient slope and capacity to readily remove all waste from the various processing operations. Where a public sewer is not available, all wastes shall be properly disposed of so as not to contaminate milk equipment or to create a nuisance or public health hazard. Containers used for the collection and holding of wastes shall be constructed of metal, plastic, or other equally impervious material and kept covered with tight-fitting lids and placed outside the plant on a concrete slab or on a rack raised at least 12 inches. Alternatively waste containers may be kept inside a suitably enclosed, clean and flyproof room. Solid wastes shall be disposed of regularly and the containers cleaned before reuse. Accumulation of dry wastepaper and cardboard shall be kept to a minimum. The paper shall be burned at the plant in a properly constructed incinerator, or compressed or bagged and hauled away.

E 1.4 *Equipment and utensils*—(a) *General construction, repair, and installation.* (1) The equipment and utensils used for the processing of milk and manufacture of dairy products shall be constructed to be readily demountable where necessary for cleaning and sanitizing. The product contact surfaces of all utensils and equipment such as holding tanks, pasteurizers, coolers, vats, agitators, pumps, sanitary piping, and fittings or any specialized equipment shall be constructed of stainless steel, or other equally corrosion-resistant material. Nonmetallic parts other than glass having product contact surfaces shall meet 3–A Sanitary Standards for Plastic or Rubber and Rubberlike Materials.

(2) All equipment and piping shall be designed and installed so as to be easily accessible for cleaning, and shall be kept in good repair, free from cracks and corroded surfaces. New or rearranged equipment shall be set away from any wall or spaced in such a manner as to facilitate proper cleaning and to maintain good housekeeping. All parts or interior surfaces of equipment, pipes (except certain piping cleaned in place) or fittings, including valves and connections, shall be accessible for inspection. Milk and dairy product pumps shall be of a sanitary type and easily dismantled for cleaning or shall be of specially approved construction to allow effective cleaning in place.

(3) All CIP systems shall comply with the 3–A Sanitary Practices for Permanently Installed Sanitary Product, Pipelines, and Cleaning Systems.

(b) *Weigh cans and receiving tanks.* Weigh cans and receiving tanks shall meet the 3–A Sanitary Standards and shall be easily accessible for cleaning both inside and outside and shall be elevated above the floor and protected sufficiently with the necessary

covers or baffles to prevent contamination from splash, condensate, and drippage. Where necessary to provide easy access for cleaning of floors and adjacent wall areas, the receiving tank shall be equipped with wheels or casters to allow easy removal.

(c) *Can washers.* Can washers shall have sufficient capacity and ability to discharge a clean, dry can and cover and shall be kept properly timed in accordance with the instructions of the manufacturer. The water and steam lines supplying the washer shall maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves.

(d) *Product storage tanks or vats.* Storage tanks or vats shall be fully enclosed or tightly covered and well insulated. The entire interior surface, agitator and all appurtenances shall be accessible for thorough cleaning and inspection. Any opening at the top of the tank or vat including the entrance of the shaft shall be suitably protected against the entrance of dust, moisture, insects, oil, or grease. The sight glasses, if used, shall be sound, clear, and in good repair. Vats which have hinged covers shall be so designed that moisture or dust on the surface cannot enter the vat when the covers are raised. If the storage tanks or vats are equipped with air agitation, the system shall be of an approved type and properly installed in accordance with the 3–A Accepted Practices for Supplying Air Under Pressure. Storage tanks or vats intended to hold product for longer than approximately 8 hours shall be equipped with adequate refrigeration and/or have adequate insulation. All new storage tanks or vats shall meet the appropriate 3–A Sanitary Standards and shall be equipped with thermometers in good operating order.

(e) *Separators.* All product contact surfaces of separators shall be free from rust and pits and insofar as practicable shall be of stainless steel or other equally noncorrosive metals.

(f) *Coil or dome-type batch pasteurizers.* Coil or dome-type batch pasteurizers shall be stainless steel lined and if the coil is not stainless steel or other equally noncorrosive metal it shall be properly tinned over the entire surface. Sanitary seal assemblies at the shaft ends of coil vats shall be of the removable type, except that existing equipment not provided with this type gland will be acceptable if the packing glands are maintained and operated without adverse effects. New or replacement units shall be provided with removable packing glands. Dome-type pasteurizer agitators shall be stainless steel except that any nonmetallic parts shall meet 3–A Sanitary Standards for Plastic or Rubber and Rubberlike Materials, as applicable. Each pasteurizer used for heating product at 165° F. or lower for 30 minutes or less shall be equipped with space heating equipment and the necessary thermometers to insure a temperature at least 5° F. above that required for pasteurization of the product. There shall be adequate means of controlling the temperature of the heating medium. Batch pasteurizers shall have temperature indicating and recording devices.

(g) *High-temperature, short-time pasteurizers.* When pasteurization is intended or required, an approved timing pump or device recorder-controller, automatic flow diversion valve and holding tube or its equivalent, if not a part of the existing equipment, shall be installed on all HTST equipment used for pasteurization, to assure complete pasteurization. The entire facility shall meet the 3–A Accepted Practices for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature, Short-Time Pasteurizers. After the HTST unit has been tested according to the 3–A Accepted Practices, the timing pump or device and the recorder controller shall be sealed at the correct setting to assure pasteurization. Sealing of the HTST unit shall be performed by the control authority having jurisdiction. The HTST pasteurizer shall be tested initially upon installation, and whenever any alteration or replacement is made which affects the proper operation of the instrument or device. When direct steam pasteurizers are used, the steam, prior to entering the product, shall be conducted through a steam strainer and a steam purifier equipped with a steam trap and only steam meeting the requirements for culinary steam shall be used.

(h) *Thermometers and recorders*—(1) *Indicating thermometers.* (i) Long-stem indicating thermometers which are accurate within 0.5° F., plus or minus, for the applicable temperature range, shall be provided for checking the temperature of pasteurization and cooling of products in vats and checking the accuracy of recording thermometers.

(ii) Short-stem indicating thermometers, which are accurate within 0.5° F., plus or minus, for the applicable temperature range, shall be installed in the proper stationary position in all HTST, and dome-type pasteurizers. Storage tanks where temperature readings are required shall have thermometers which are accurate within 2.0° F., plus or minus.

(iii) Air-space indicating thermometers, where applicable, which are accurate within 1.0° F., plus or minus, for the proper temperature range shall also be installed above the surface of the products pasteurized in vats, to make certain that the temperature of the foam and/or air above the products pasteurized also received the required minimum temperature treatment.

(2) *Recording thermometers.* (i) HTST recording thermometers that are accurate within 1° F., plus or minus, for the applicable temperature range, shall be used on each heat treating, pasteurizing, or sterilizing unit to record the heating process.

(ii) Additional use of recording thermometers accurate within 2° F., plus or minus, may be required where a record of temperature or time of cooling and holding is of significant importance.

(i) *Surface coolers.* Surface coolers shall be equipped with hinged or removable covers for the protection of the product. The edges of the fins shall be so designed as to divert condensate on nonproduct contact surfaces away from product contact surfaces. All gaskets or swivel connections shall be leak proof.

(j) *Plate-type heat exchangers.* Plate-type heat exchangers shall meet the 3–A Sanitary Standards for Construction and Installation. All gaskets shall be tight and kept in good operating order. Plates shall be opened for inspection by the operator at sufficiently frequent intervals to determine if the equipment is clean and in satisfactory condition. A cleaning regimen shall be posted to insure proper cleaning procedures between inspection periods.

(k) *Internal return tubular heat exchangers.* Internal return tubular heat exchangers shall meet the 3–A Sanitary Standards for Construction and Installation.

(l) *Pumps.* Pumps used for milk and dairy products shall be of the sanitary type and constructed to meet 3–A Sanitary Standards. Unless pumps are specifically designed for effective cleaning in place they shall be disassembled and thoroughly cleaned after use.

(m) *Homogenizers.* Homogenizers and high pressure pumps of the plunger type shall meet the 3–A Sanitary Standards.

(n) *New equipment and replacements.* New equipment and replacements, including all plastic parts and rubber and rubberlike materials for parts and gaskets having product contact surfaces, shall meet the then current 3–A Sanitary Standards. If 3–A Sanitary Standards are not available, such equipment and replacements shall meet the general requirements of this section.

(o) *Vacuum chamber.* The vacuum chamber, as used for flavor control, shall be made of stainless steel or other equally noncorrosive metal. The unit shall be constructed to facilitate cleaning and all product contact surfaces shall be accessible for inspection. It shall be equipped with a vacuum breaker and a check valve at the product discharge line. Only steam which meets the requirements for culinary steam shall be used. The incoming steam supply shall be regulated by an automatic solenoid valve which will cut off the steam supply in the event the flow diversion valve of the HTST pasteurizer is not in the forward flow position. Condensers when used shall be equipped with a water level control and an automatic safety shutoff valve.

E 1.5 *Personnel cleanliness.* All employees shall wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking, or otherwise soiling their hands. They shall keep their hands clean and follow good hygienic practices while on duty. Expectorating or use of tobacco in any form shall be prohibited in each room and compartment where any milk, dairy product, or supplies are prepared, stored, or otherwise handled. Clean white or light-colored washable outer garments and caps (paper caps or hair nets acceptable) shall be worn by all persons engaged in receiving, testing,

processing milk, manufacturing, packaging, or handling dairy products.

E 1.6 *Personnel health.* No person afflicted with a communicable disease shall be permitted in any room or compartment where milk and dairy products are prepared, manufactured, or otherwise handled. No person who has a discharging or infected wound, sore or lesion on hands, arms, or other exposed portion of the body shall work in any dairy processing rooms or in any capacity resulting in contact with milk or dairy products. Each employee whose work brings him in contact with the processing or handling of dairy products, containers, or equipment shall have a medical and physical examination by a registered physician or by the local department of health at the time of employment. In addition an employee returning to work following illness from a communicable disease shall have a certificate from the attending physician to establish proof of complete recovery. Medical certificates attesting the fact that the employee when last examined was free from communicable disease shall be kept on file at the plant office.

E 1.7 *Protection and transport of raw milk and cream*—(a) *Equipment and facilities*—(1) *Milk cans.* Cans used in transporting milk from dairy farm to plant shall be of such construction (preferably seamless with umbrella lids) as to be easily cleaned, and shall be inspected, repaired, and replaced as necessary to exclude substantially the use of cans and lids with open seams, cracks, rust milkstone, or any unsanitary condition.

(2) *Farm bulk tanks.* New farm bulk tanks shall meet 3–A Sanitary Standards for construction and shall be installed in accordance with the requirements of the regulatory agency in jurisdiction.

(b) *Transporting milk or cream*—(1) *Vehicles.* Vehicles used for the transportation of can milk or cream shall be of the enclosed type, constructed and operated to protect the product from extreme temperature, dust, or other adverse conditions and they shall be kept clean. Decking boards or racks shall be provided where more than one tier of cans is carried. Cans, or bulk tanks on vehicles, used for the transportation of milk from the farm to the plant shall not be used for any other purpose.

(2) *Transport tanks.* The exterior shell shall be clean and free from open seams or cracks which would permit liquid to enter the jacket. The interior shell shall be stainless steel and so constructed that it will not buckle, sag, or prevent complete drainage. All product contact surfaces shall be smooth, easily cleaned, and maintained in good repair. The pump and hose cabinet shall be fully enclosed with tight fitting doors and the inlet and outlet shall be provided with dust covers to give adequate protection from road dust. New and replacement transport tanks shall meet 3–A Sanitary Standards for Milk Transport Tanks.

(c) *Facilities for cleaning and sanitizing.* Enclosed or covered facilities shall be available for washing and sanitizing of transport tanks, piping and accessories, at central locations or at all plants that receive or ship milk or milk products in transport tanks.

(d) *Transfer of milk to transport tank.* Milk shall be transferred under sanitary conditions from farm bulk tanks through stainless steel piping or approved tubing. The sanitary piping and tubing shall be capped when not in use.

E 1.8 *Raw product storage.* (a) All milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Drip milk from can washers or any other source shall not be used for the manufacture of dairy products. Bulk milk in storage tanks within the dairy plant shall be handled in such a manner as to minimize bacterial increase and shall be maintained at 45° F. or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

(b) The bacteriological quality of commingled milk in storage tanks shall be 3 million or lower.

E 1.9 *Pasteurization or sterilization.* When pasteurization or sterilization is intended or required, or when a product is designated "pasteurized" or "sterilized" every particle of the product shall be subjected to such temperatures and holding periods as will assure proper pasteurization or sterilization of the product. The heat treatment by either process shall be sufficient to insure public health safety and to assure adequate keeping quality, yet retaining the most desirable flavor and body characteristics of the finished product. The phenol value of test samples of pasteurized finished product shall be no greater than the maximum specified for the particular product as determined and specified by the phosphatase test method prescribed in the latest edition of "Official Methods of Analysis of the Association of Official Agricultural Chemists."

E 1.10 *Composition and wholesomeness.* All necessary precautions shall be taken to prevent contamination or adulteration of the milk or dairy products during manufacturing. All substances and ingredients used in the processing or manufacturing of any dairy product shall be subject to inspection and shall be wholesome and practically free from impurities. The finished product shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act as to their composition and wholesomeness.

E 1.11 *Cleaning and sanitizing treatment*—(a) *Equipment and utensils.* (1) The equipment, sanitary piping and utensils used in receiving and processing of the milk, and manufacturing and handling of the product shall be maintained in a sanitary condition. Sanitary seal assemblies shall be removable on all agitators, pumps and vats, and shall be inspected at regular intervals and kept clean. Unless other provisions are recommended in the following supplemental sections, all equipment not designed for C.I.P. cleaning shall be disassembled after each day's use for thorough cleaning. Dairy cleaners, detergents, wetting agents, sanitizing agents or other similar materials which will not contaminate or adversely affect the products may be used. Steel wool or metal sponges shall not be used in the cleaning of any dairy equipment or utensils. All product contact surfaces shall be subjected to an effective sanitizing treatment immediately prior to use, except where dry cleaning is permitted. Utensils and portable equipment used in processing and manufacturing operations shall be stored above the floor in clean, dry locations and in a self draining position on racks constructed of impervious corrosion-resistant material.

(2) C.I.P. cleaning, including sprayball systems, shall be used only on equipment and pipeline systems which have been designed and engineered for that purpose. When such cleaning is used, careful attention shall be given to the proper procedures to assure satisfactory cleaning. All C.I.P. installations and cleaning procedures shall be in accordance with 3–A Suggested Methods for the Installation and Cleaning of Cleaned-In-Place Sanitary Milk Pipelines for Milk and Milk Products Plants. The established cleaning procedure shall be posted and followed. Following the circulation of the cleaning solution the equipment and lines shall be thoroughly rinsed with lukewarm water and checked for effectiveness of cleaning. All caps, plugs, special fittings, valve seats, cross ends, pumps, plates, and tee ends shall be opened or removed and brushed clean. Immediately prior to starting the product flow, the product contact surfaces shall be given bactericidal treatment.

(b) *Milk cans and can washers.* (1) Milk cans and lids shall be cleaned, sanitized, and dried before returning to producers. Inspection, repair, or replacement of cans and lids shall be adequate to substantially exclude from use cans and lids showing open seams, cracks, rust condition, milkstone or any unsanitary condition.

(2) Washers shall be maintained in a clean and satisfactory operating condition and kept free from accumulation of scale or debris which will adversely affect the efficiency of the washer.

(c) *Milk transport tanks.* A covered or enclosed wash dock and cleaning and sanitizing facilities shall be available to all plants that receive or ship milk in tanks. Milk transport tanks, sanitary piping, fittings, and pumps shall be cleaned and sanitized at least once each day, after use: *Provided,* That if they are not to be used immediately after emptying a load of milk, they shall be washed promptly after use and given bactericidal treatment immediately before use. After being washed and sanitized, each tank shall be identified by a tag attached to the outlet valve, bearing the following information: Plant and specific location where cleaned, date and time of day of washing and sanitizing, and name of person who washed and name of person who sanitized the tank. The tag shall

not be removed until the tank is again washed and sanitized.

(d) *Building.* All windows, glass, partitions, and skylights shall be washed as often as necessary to keep them clean. Cracked or broken glass shall be replaced promptly. The walls, ceilings, and doors shall be washed periodically and kept free from soil and unsightly conditions. The shelves and ledges shall be wiped or vacuumed as often as necessary to keep them free from dust and debris. The material picked up by the vacuum cleaners shall be disposed of by burning or other proper methods to destroy any insects that might be present.

E 1.12 *Insect and rodent control program.* In addition to any commercial pest control service, if one is utilized, a specially designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program. Poisonous substances, insecticides, and rodenticides shall be properly labeled, and shall be handled, stored, and used in such a manner as not to create a public health hazard.

E 1.13 *Plant records.* Adequate plant records shall be maintained of all required tests on all raw milk receipts. Such records shall be available for examination at all reasonable times by the inspector. The following are the records which shall be maintained for examination at the plant or receiving station where performed.

(a) Sediment and bacterial test results on raw milk from each producer: Retain for 12 months.

(1) Routine tests and monthly summary of all producers showing number and percent of total in each class.

(2) Retests, if initial test places milk in probationary status.

(3) Rejections of raw milk over No. 3 in quality.

(b) Pasteurization recorder charts: Retain for 6 months.

(c) Water supply test certificate: Retain current copy for 6 months.

(d) Employee health certificate: Retain most recent copy until employee is no longer employed by plant.

E 1.14 *Packaging and general identification*—(a) *Containers.* (1) The size, style, and type of packaging used for dairy products shall be commercially acceptable containers and packaging materials which will satisfactorily cover and protect the quality of the contents during storage and regular channels of trade and under normal conditions of handling. The weights and shape within each size or style shall be as nearly uniform as is practical.

(2) Packaging materials for dairy products shall be selected which will provide sufficiently low permeability to air and vapor to prevent the formation of mold growth and surface oxidation. In addition, the wrapper should be resistant to puncturing, tearing, cracking, or breaking under normal conditions of handling, shipping, and storage. When special-type packaging is used, the instructions of the manufacturers shall be followed closely as to its application and methods of closure.

(b) *Packaging and repackaging.* Packaging dairy products or cutting and repackaging all styles of dairy products shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and packaging material shall be practically free from mold and bacterial contamination. Methods for checking the level of contamination shall be as prescribed by the latest edition of Standard Methods.

(c) *General identification.* All commercial bulk packages containing dairy products manufactured under the provisions of this subpart shall be adequately and legibly marked with the name of the product, net weight, name and address of processor or manufacturer or other assigned plant identification, lot number, and any other identification as may be required. Consumer packaged product shall be legibly marked with the name of the product, net weight, name and address of packer, manufacturer, or distributor and such other identification as may be required by the regulatory agency in jurisdiction.

E 1.15 *Storage of finished product*—(a) *Dry storage.* The product shall be stored at least 18 inches from the wall in aisles, rows, or sections and lots, in such a manner as to be orderly and easily accessible for inspection. Rooms should be cleaned regularly. Care shall be taken in the storage of any other product foreign to dairy products in the same room, in order to prevent impairment or damage to the dairy product from mold, absorbed odors, or vermin or insect infestation. Control of humidity and temperature shall be maintained at all times, consistent with good commercial practices, to prevent conditions detrimental to the product and container.

(b) *Refrigerated storage.* The finished product shall be placed on shelves, dunnage, or pallets and properly identified. It shall be stored under temperatures that will best maintain the initial quality. The product shall not be exposed to anything from which it might absorb any foreign odors or be contaminated by drippage or condensation.

E 1.16 *Qualifications for plant licensing.* Plant licensing requires satisfactory compliance with the applicable requirements in Subpart E.

SEC. E 2. *Supplemental requirements for plants manufacturing, processing and packaging instant nonfat dry milk, nonfat dry milk, dry whole milk, dry buttermilk, dry whey, and other dry milk products*—E 2.1 *Rooms and compartments*—E 2.1.1 *Dry storage of product.* Storage rooms for the dry storage of product shall be adequate in size, kept clean, orderly, free from rodents, insects, and mold, and maintained in good repair. They shall be adequately lighted and ventilated. The ceilings, walls, beams, and floors shall be free from structural defects and inaccessible false areas which may harbor insects.

E 2.1.2 *Packaging room for bulk products.* A separate room or area shall be provided for filling bulk bins, drums, bags, or other bulk containers and shall be constructed in accordance with section 1.2 of Subpart E. The number of control panels and switchboxes in this area shall be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or shall be mounted in the wall and provided with tight-fitting removable doors to facilitate cleaning. An adequate exhaust system shall be provided to minimize the accumulation of product dust within the packaging room and, where needed, a dust collector shall be provided and properly maintained to keep roofs and outside areas free of dry product. Only packaging materials that are used within a day's operation may be kept in the packaging area. These materials shall be kept on metal racks or tables at least 6 inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, shall not be allowed in the packaging room.

E 2.1.3 *Hopper or dump room.* A separate room shall be provided for the transfer of bulk dry dairy products from bags or drums to the hoppers and conveyors which lead to the fillers. This room shall meet the same requirements for construction and facilities as the bulk packaging operation. Areas and facilities provided for the transfer of dry dairy products from portable bulk bins will be acceptable if gasketed surfaces or direct connections are used that appreciably eliminate the escape of product into the area.

E 2.1.4 *Repackaging room.* A separate room shall be provided for the filling of small packages and shall meet the same requirements for construction and facilities as the bulk packaging operation.

E 2.2 *Equipment and utensils*—E 2.2.1 *General construction, repair, and installation.* All equipment and utensils necessary to the manufacture of dry milk products, including pasteurizer, timing pump or device, flow diversion valve and recorder controller, shall meet the same general requirements as outlined in section 1.4 of Subpart E. In addition, for certain other equipment the following requirements shall be met.

E 2.2.2 *Preheaters.* The preheaters shall be of stainless steel or other equally corrosion-resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

E 2.2.3 *Hotwells.* The hotwells shall be enclosed or covered and equipped with indicating thermometers either in the hotwell or in the hot milk inlet line to the hotwell and if used for holding high heat products they should also have recorders.

E 2.2.4 *Evaporators and/or vacuum pans.* Open-type evaporators and/or vacuum pans shall be equipped with an automatic condenser water level control, barometric leg, or so constructed so as to prevent water from entering the product, and should meet the applicable 3–A Sanitary Standards. When enclosed-type condensers are used, no special controls are needed to prevent water from entering the product.

E 2.2.5 *Surge tanks.* If surge tanks are used for hot milk and temperatures of

product including foam being held in the surge tank during processing is not maintained at a minimum of 150° F., then two or more surge tanks shall be installed with cross connections to permit flushing and cleaning during operation. Covers easily removable for cleaning shall be provided and used at all times.

E 2.2.6 *High pressure pumps and lines.* High pressure lines may be cleaned in place and shall be of such construction that deadends, valves and the high pressure pumps can be disassembled for hand cleaning. New high pressure pumps shall meet the 3–A Sanitary Standard Covering Homogenizers and High Pressure Pumps of the Plunger Type.

E 2.2.7 *Dryers*—(a) *Spray dryers.* Spray dryers shall be of a continuous discharge type and all product contact surfaces shall be of stainless steel or other equally corrosion-resistant material. All joints and seams in the product contact surfaces shall be welded and ground smooth. All dryers shall be constructed so as to facilitate ease in cleaning and inspection. Sight glasses or ports of sufficient size shall be located at strategic positions. Dryers shall be equipped with suitable air intake filters and with air intake and exhaust recording thermometers. The filter system shall consist of filtering media or devices that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying chamber. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. In gas-fired dryers, precautions shall be taken to assure complete combustion. Air shall be drawn into the dryer from sources free from objectionable odors and smoke, dust, or dirt.

(b) *Roller dryers.* (1) The drums of a roller dryer shall be smooth, readily cleanable and free of pits and rusts. The knives shall be maintained in such condition so as not to cause scoring of the drums.

(2) The end boards shall have an impervious surface and be readily cleanable. They shall be provided with a means of adjustment to prevent leakage and accumulation of milk solids. The stack, hood, the drip pan inside of the hood and related shields shall be constructed of stainless steel and be readily cleanable. The lower edge of the hood shall be constructed so as to prevent condensate from entering the product zone. The hood shall be properly located and the stack of adequate capacity to remove the vapors. The stack shall be closed when the dryer is not in operation. The augers shall be of stainless steel or properly plated, and readily cleanable. The auger troughs and related shields shall be of stainless steel and be readily cleanable. All air entering the dryer room shall be filtered to eliminate dust and dirt. The filter system shall consist of filtering media or device that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying room. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. All dryer adjustments shall be made and the dryer operating normally before food grade powder can be collected from the dryer.

E 2.2.8 *Collectors and conveyors.* Collectors shall be made of stainless steel or equally noncorrosive material and should be constructed to facilitate cleaning and inspection. Filter sack collectors, if used, shall be in good condition and the system shall be of such construction that all parts are accessible for cleaning and inspection. Conveyors shall be of stainless steel or equally corrosion-resistant material and shall be constructed to facilitate thorough cleaning and inspection.

E 2.2.9 *Dry dairy product cooling equipment.* Cooling equipment shall be provided with sufficient capacity to cool the product to 110° F. or lower immediately after removal from dryer and prior to packaging. If bulk bins are used, the product should be cooled to approximately 90° F. but shall be not more than 110° F. A suitable dry air supply with effective filtering shall be provided where air cooling and conveying is used.

E 2.2.10 *Special treatment equipment.* All special equipment such as instantizing systems, flakers, pulverizers or hammer mills used to further process dry milk products shall be of sanitary construction and all parts shall be accessible for cleaning and inspection.

E 2.2.11 *Sifters.* All newly installed sifters used for dry milk and dry milk products shall meet the 3–A Sanitary Standards for Sifters for Dry Milk and Dry Milk Products. All other sifters shall be constructed of stainless steel or other equally noncorrosive material and shall be of sanitary construction and accessible for cleaning and inspection. The mesh size of sifter screen used for various dry dairy products shall be those recommended in the appendix of the 3–A Standard for sifters.

E 2.2.12 *Portable and stationary bulk bins.* Bulk bins shall be constructed of stainless steel, aluminum or other equally corrision resistant materials, free from cracks and seams and must have an interior surface that is relatively smooth and easily cleanable. All product contact surfaces shall be easily accessible for cleaning.

E 2.2.13 *Automatic sampling device.* If automatic sampling devices are used, they shall be constructed in such a manner as to prevent contamination of the product, and all parts must be readily accessible for cleaning.

E 2.2.14 *Dump hoppers, screens, mixers, and conveyors.* The product contact surfaces of dump hoppers, screens, mixers, and conveyors which are used in the process of transferring dry products from bulk containers to fillers for small packages or containers, shall be of stainless steel or equally corrosion resistant material and designed to prevent contamination. All parts should be accessible for cleaning. The dump hoppers shall be of such height above floor level as to prevent foreign material or spilled product from entering the hopper.

E 2.2.15 *Filler and packaging equipment.* All filling and packaging equipment shall be of sanitary construction and all parts, including valves and filler heads, accessible for cleaning.

E 2.2.16 *Heavy duty vacuum cleaners.* Each plant handling dry milk products shall be equipped with a heavy duty industrial vacuum cleaner. Regular scheduling shall be established for its use in vacuuming applicable areas.

E 2.3 *Clothing and shoe covers.* Clean clothing and shoe covers shall be provided exclusively for the purpose of cleaning the interior of the drier when it is necessary to enter the drier to perform the cleaning operation.

E 2.4 *Operations and operating procedures*—E 2.4.1 *Pasteurization* (1) All milk, buttermilk and whey used in the manufacture of dry dairy products shall be pasteurized at the plant where dried, except that condensed whey and acidified buttermilk containing 40 percent or more solids may be transported to another plant for drying without repasteurization. Milk or skim milk to be used in the manufacture of nonfat dry milk shall be heated prior to condensing to at least the minimum pasteurization temperature of 161° F. for at least 15 seconds or its equivalent in bacterial destruction. Condensed skim made from pasteurized skim milk may be transported to a drying plant, provided that it shall be effectively repasteurized at the drying plant, prior to drying, at not less than 175° F. for 25 seconds or its equivalent in bacterial destruction.

(2) All buttermilk or cream from which it is derived shall be pasteurized prior to condensing at a temperature of 185° F. for 15 seconds or its equivalent in bacterial destruction.

(3) All cheese whey or milk from which it is derived shall be pasteurized prior to condensing at a temperature of 161° F. for 15 seconds or its equivalent in bacterial destruction.

E 2.4.2 *Condensed surge supply.* Surge tanks or balance tanks if used between the evaporators and dryer shall be used to hold only the minimum amount of condensed product necessary for a uniform flow to the dryers. Such tanks holding product at temperatures below 150° F. shall be completely emptied and washed after each 4 hours of operation or less. Alternate tanks shall be provided to permit continuous operation during washing of tanks.

E 2.4.3 *Condensed storage tanks.* (1) Excess production of condensed product over that which the dryer will take continuously from the pans should be bypassed through a cooler into a storage tank at 50° F. or lower and held at this temperature until used.

(2) Product cut-off points shall be made at least every 24 hours and the tank completely emptied, washed, and sanitized before reuse.

E 2.4.4 *Drying.* Each dryer should be operated at not more than the manufacturer's rated capacity for the highest quality dry product consistent with the most efficient operation. This does not preclude the remodeling or redesigning

of dryers after installation when properly engineered and designed. The dry products shall be removed from the drying chamber continuously during the drying process.

E 2.4.5 *Cooling dry products.* Prior to packaging and immediately following removal from the drying chamber the dry product shall be cooled to a temperature not exceeding 110° F.

E 2.4.6 *Packaging, repackaging and storage*—(a) *Containers.* Packages or containers used for the packaging of nonfat dry milk or other dry milk products shall be any clean, sound commercially accepted container or packaging material which will satisfactorily protect the contents through the regular channels of trade, without significant impairment of quality with respect to flavor, wholesomeness or moisture content under the normal conditions of handling. In no instance will containers which have previously been used for nonfood items or food which would be deleterious to the dairy product be allowed to be used for the bulk handling of dairy products.

(b) *Filling.* Empty containers shall be protected at all times from possible contamination and containers which are to be lined shall not be prepared more than 1 hour in advance of filling. Every precaution shall be taken during the filling operation to minimize product dust and spillage. When necessary a mechanical shaker shall be provided; the tapping or pounding of containers shall be prohibited. The containers shall be closed immediately after filling and the exteriors shall be vacuumed or brushed when necessary to render them practically free of product remnants before being transferred from the filling room to the palleting or dry storage areas.

(c) *Repackaging.* The entire repackaging operation shall be conducted in a sanitary manner with all precautions taken to prevent contamination and to minimize dust. All exterior surfaces of individual containers shall be practically free of product before overwrapping or packing in shipping containers. The flow shall be kept free of dust accumulation, waste, cartons, liners, or other refuse. Conveyors, packaging and cartonmaking equipment shall be vacuumed frequently during the operating day to prevent the accumulation of dust. No bottles or glass materials of any kind shall be permitted in the repackaging or hopper room. The inlet openings of all hoppers and bins shall be of minimum size, screened and placed well above the floor level. The room and all packaging equipment shall be cleaned as often as necessary to maintain a sanitary operation. Close attention shall be given to cleaning points of equipment where residues of the dry product may accumulate. A thorough cleanup including windows, doors, walls, light fixtures, and ledges, shall be performed as frequently as is necessary to maintain a high standard of cleanliness and sanitation. All waste dry dairy products including dribble product at the fillers shall be properly identified and disposed of as animal feed.

(d) *Storage*—(1) *Product.* The packaged dry milk product shall be stored or so arranged in aisles, rows, or sections and lots at least 18 inches from any wall and in such a manner as to be orderly, easily accessibile for inspection or for cleaning of the room. All bags and small containers of product shall be placed on pallets elevated approximately 6 inches from the floor. The storage room shall be kept clean and dry and all openings protected against entrance of insects and rodents.

(2) *Supplies.* All supplies shall be placed on dunnage or pallets and arranged in an orderly manner for accessibility and cleaning of the room. Supplies shall be kept enclosed in their original wrapping material until used. After removal of supplies from their original containers they shall be kept in an enclosed metal cabinet, bins, or on shelving and if not enclosed shall be protected from powder and dust or other contamination. The room shall be vacuumed as often as necessary and kept clean and orderly.

E 2.4.7 *Product adulteration.* All necessary precautions shall be taken throughout the entire operation to prevent the adulteration of one product with another. The commingling of one type of liquid or dry product with another shall be considered as an adulteration of that product. This does not prohibit the normal standardization of like products in accordance with good commercial practices or the production of specific products for special uses, provided applicable labeling requirements are met.

E 2.4.8 *Checking quality.* All mink, milk products, and dry milk products shall be subject to inspection and analysis by the dairy plant for quality and condition throughout each processing operation. Line samples shall be taken periodically as an aid to quality control in addition to the regular routine analysis made on the finished products.

E 2.4.9 *Requirements for instant nonfat dry milk*—(a) *Sampling and testing.* All instant nonfat dry milk offered for sale shall be sampled and tested by the regulatory authority at least once each month for the purpose of assuring that the product meets the requirements of section E 2.4.9(b). In addition the dry milk plant shall have each sublot of approximately 4,000 pounds tested and analyzed prior to being packaged or offered for sale. Product not meeting the requirements of section E 2.4.9(b) shall not be offered as Extra Grade.

(b) *Requirements for Extra Grade instant nonfat dry milk*—(1) *Flavor and odor.* The flavor and odor shall be sweet, pleasing and desirable but may possess the following flavors to a slight degree: Chalky, cooked, feed, flat.

(2) *Physical appearance.* The physical appearance shall possess a uniform white to light cream natural color; shall be reasonably free-flowing and free from lumps except those that readily break up with very slight pressure.

(3) *Bacterial estimate.* The standard plate count shall not be more than 30,000 per gram.

(4) *Coliform count.* The coliform count shall not be more than 10 per gram.

(5) *Milkfat content.* The milkfat shall not be more than 1.25 percent.

(6) *Moisture count.* The moisture shall not be more than 4.5 percent.

(7) *Scorched particle content.* Scorched particles shall not be more than 15 mg.

(8) *Solubility index.* The solubility index shall not be more than 1 ml.

(9) *Titratable acidity.* The titratable acidity shall not be more than 0.15 percent.

(10) *Dispersibility.* The dispersibility shall not be less than 85 percent by the Modified Moats-Dabbah Method.

(11) *Direct microscopic clump count.* The direct miscroscopic clump count shall not be more than 75 million per gram.

E 2.4.10 *Cleaning of dryers, conveyors, sifters, and storage bins.* This equipment shall be cleaned as often as is necessary to maintain such equipment in a clean and sanitary condition. The kind of cleaning procedure either wet or dry and the frequency of cleaning shall be based upon observation of actual operating results and conditions.

E 2.4.11 *Insect and rodent control program.* In addition to any commercial pest control service, if one is utilized, a specially designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program.

SEC. E 3. *Supplemental requirements for plants manufacturing, processing and packaging butter and related products*—E 3.1 *Rooms and compartments*—E 3.1.1 *Coolers and freezers.* The coolers and freezers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the quality and condition of the products during storage or during tempering prior to further processing. Coolers and freezers shall be kept clean, orderly, free from insects, rodents, and mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

E 3.1.2 *Churn rooms.* Churn rooms in addition to proper construction and sanitation shall be so equipped that the air is kept free from objectionable odors and vapors and extreme temperatures by means of adequate ventilation and exhaust systems or air conditioning and heating facilities.

E 3.1.3 *Print and bulk packaging rooms.* Rooms used for packaging print or bulk butter and related products shall, in addition to proper construction and sanitation, provide an atmosphere relatively free from mold (no more than 10 mold colonies per cubic foot of air), dust, or other airborne contamination and be maintained at a reasonable room temperature.

E 3.2 *Equipment and utensils*—E 3.2.1 *General construction, repair, and installation.* All equipment and utensils necessary to the manufacture of butter and related products shall meet the same general requirements as outlined in section 1.4 of subpart E 1. In addition for certain other equipment, the following requirements shall be met.

E 3.2.2 *Continuous churn.* All product contact surfaces shall be of noncorrosive material. All nonmetallic product contact surfaces shall comply with 3–A Standards for Plastic, Rubber, and Rubber-Like Materials. All product contact surfaces shall be readily accessible for cleaning and inspection.

E 3.2.3 *Conventional churn.* Churns shall be constructed of aluminum, stainless steel or equally corrosion resistant metal, free from cracks, and in good repair. All gasket material shall be fat resistant, nontoxic and reasonably durable. Seals around the doors shall be tight.

E 3.2.4 *Bulk butter trucks, boats and packers.* Bulk butter trucks, boats and packers shall be constructed of aluminum, stainless steel or equally corrosion resistant metal free from cracks, seams and must have a surface that is relatively smooth and easily cleanable.

E 3.2.5 *Butter, frozen or plastic cream melting machine.* Shavers, shredders or melting machines used for rapid melting of butter, frozen or plastic cream shall be of stainless steel or equally corrosion resistant metal, sanitary construction, and readily cleanable.

E 3.2.6 *Printing equipment.* All printing equipment shall be designed to be readily demountable for cleaning of product contact surfaces. All product contact surfaces shall be aluminum, stainless steel or equally corrosion resistant metal, or plastic, rubber and rubber like material which meet 3–A standards, except that conveyors may be constructed of material which can be properly cleaned and maintained in a satisfactory manner.

E 3.2.7 *Brine tanks.* Brine tanks used for the treating of parchment liners shall be constructed of noncorrosive material and have an adequate and safe means of heating the salt solution for the treatment of the liners. The tank shall also be provided with a satisfactory drainage outlet.

E 3.2.8 *Starter vats.* Bulk starter vats shall be of stainless steel or equally corrosion-resistant metal and constructed according to applicable 3–A Sanitary Standards. The vats shall be in good repair, equipped with tight-fitting lids, and have effective temperature controls.

E 3.3 *Operations and operating procedures*—E 3.3.1 *Pasteurization.* The milk or cream shall be pasteurized at the plant where the milk or cream is processed into the finished product.

(a) *Cream for buttermaking.* (1) The cream for buttermaking shall be pasteurized at a temperature of not less than 165° F. and held continuously in a vat at such temperature for not less than 30 minutes; or pasteurized by HTST method at a minimum temperature of not less than 185° F. for not less than 15 seconds; or by any other equivalent time and temperature combination. Additional heat treatment above the minimum pasteurization requirement is advisable to insure improved keeping-quality characteristics.

(2) Adequate pasteurization control shall be used and the diversion valve shall be set to divert at no less than 185° F. with a 15-second holding time or its equivalent in time and temperature to assure pasteurization. If the vat or holding method of pasteurization is used, vat covers shall be closed prior to holding period to assure temperature of air space reaching the minimum temperature before holding time starts. Covers shall also be kept closed during the holding and cooling period.

(b) *Cream for plastic or frozen cream.* The pasteurization of cream for plastic or frozen cream shall be accomplished in the same manner as in (a) above, except, that the temperature for the vat method shall be not less than 170° F. for not less than 30 minutes, or not less than 190° F. for not less than 15 seconds or by any other temperature and holding time which will assure adequate pasteurization and comparable keeping-quality characteristics.

E 3.3.2 *Composition and wholesomeness.* All ingredients used in the manufacture of butter and related products shall be subject to inspection and shall be wholesome and practically free from impurities. Chlorinating facilities shall be provided for butter wash water if needed and all other necessary precautions shall be taken to prevent contamination of products. All finished products shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act, as to composition and wholesomeness.

E 3.3.3 *Containers.* (a) Containers used for the packaging of butter and related products shall be commercially acceptable containers or packaging material that will satisfactorily protect the quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing 2 pounds or less, to protect the product from contamination during subsequent handling.

(b) *Liners and wrappers.* (1) Supplies of parchment liners, wrappers, and other packaging material shall be protected against dust, mold, and other possible contamination.

(2) Prior to use, parchment liners for bulk butter packages shall be completely immersed in a boiling salt solution in a suitable container constructed of stainless steel or other equally noncorrosive material. The liners shall be maintained in the solution for not less than 30 minutes. The solution should consist of at least 15 pounds of salt for every 85 pounds of water and shall be strengthened or changed as frequently as necessary to keep the solution full strength and in good condition.

(3) Other liners such as polyethylene shall be treated or handled in such a manner as to prevent contamination of the liner prior to filling.

(c) *Filling bulk butter containers.* The lined butter containers shall be protected from possible contamination prior to filling.

E 3.3.4. *Printing and packaging.* Printing and packaging of consumer size containers of butter shall be conducted under sanitary conditions.

E 3.3.5. *General identification.* Commercial bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or distributor or other assigned plant identification (manufacturer's lot number, churn number, etc.) and any other identification that may be required. Packages of plastic or frozen cream shall be marked with the percent of milkfat.

E 3.3.6 *Storage of finished product in coolers.* All products shall be kept under refrigeration at temperatures of 40° F. or lower after packaging and until ready for distribution or shipment. The products shall not be placed directly on floors or exposed to foreign odors or conditions such as drippage due to condensation which might cause package or product damage.

E 3.3.7 *Storage of finished product in freezer*—(a) *Sharp freezers.* Plastic cream or frozen cream intended for storage shall be placed in quick freezer rooms immediately after packaging, for rapid and complete freezing within 24 hours. The packages shall be piled or spaced in such a manner that air can freely circulate between and around the packages. The rooms shall be maintained at −10° F. or lower and shall be equipped to provide sufficient high-velocity air circulation for rapid freezing. After the products have been completely frozen, they may be transferred to a freezer storage room for continued storage.

(b) *Freezer storage.* (1) The room shall be maintained at a temperature of 0° F. or lower. Adequate air circulation is desirable.

(2) Butter intended to be held more than 30 days shall be placed in a freezer room as soon as possible after packaging. If not frozen before being placed in the freezer, the packages shall be spaced in such a manner as to permit rapid freezing and repiled, if necessary, at a later time.

SEC. E 4. *Supplemental requirements for plants manufacturing and packaging cheese*—E 4.1 *Rooms and compartments*—E 4.1.1 *Starter room.* Starter rooms or areas shall be properly equipped and maintained for the propagation and handling of starter cultures. All necessary precautions shall be taken to prevent contamination of starter, of the room, equipment, and the air therein.

E 4.1.2 *Make room.* The room in which the cheese is manufactured shall be of adequate size, and the vats adequately spaced to permit movement around the vats and presses for proper cleaning and satisfactory working conditions. Adequate ventilation shall be provided.

E 4.1.3 *Drying room.* If cheese is to be paraffined, a drying room of adequate

size shall be provided to accommodate the maximum production of cheese during the flush period. Adequate shelving and air circulation shall be provided for proper drying. Suitable temperature and humidity control facilities shall be provided.

E 4.1.4 *Paraffining room.* For rind cheese, a separate room or compartment shall be provided for paraffining and boxing the cheese. The room or compartment shall be of adequate size and the temperature maintained near the temperature of the drying room to avoid sweating of the cheese prior to paraffining.

E 4.1.5 *Rindless block wrapping area.* For rindless blocks a suitable space shall be provided for proper wrapping and boxing of the cheese. The area shall be free from dust, condensation, mold or other conditions which may contaminate the surface of the cheese or contribute to an unsatisfactory packaging of the cheese.

E 4.1.6 *Coolers or curing rooms.* Coolers or curing rooms where cheese is held for curing or storage shall be clean and maintained at the proper uniform temperature and humidity to adequately protect the cheese. Proper circulation of air shall be maintained at all times. The rooms shall be free from rodents, insects, and pests. The shelves shall be kept clean and dry.

E 4.1.7 *Cutting and packaging rooms.* When small packages of cheese are cut and wrapped, separate rooms shall be provided for the cleaning and preparation of the bulk cheese and a separate room shall be provided for the cutting and wrapping operation. The rooms shall be well lighted, ventilated, and provided with filtered air. Air movement shall be outward to minimize the entrance of unfiltered air into the cutting and packaging room.

E 4.2 *Equipment and utensils*—E 4.2.1 *General construction, repair, and installation.* All equipment and utensils necessary to the manufacture of cheese and related products shall meet the same general requirements as outlined in section 1.4 of Subpart E. In addition, for certain other equipment the following requirements shall be met.

E 4.2.2 *Starter vats.* Bulk starter vats shall be of stainless steel or equally corrosion-resistant metal and shall be in good repair, equipped with tight-fitting lids and have adequate temperature controls such as valves, indicating and/or recording thermometers. New vats shall be constructed according to the applicable 3–A Sanitary Standards.

E 4.2.3 *Cheese vats.* (1) The vats used for making cheese shall be of metal construction with adequate jacket capacity for uniform heating. The inner liner shall be minimum 16-gage stainless steel or other equally corrosion-resistant metal, properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket, when metal, shall be constructed of strainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed so as to prevent milk or cheese from entering the inner jacket.

(2) The vat shall be equipped with a suitable sanitary outlet valve. Effective valves shall be provided and properly maintained to control the application of heat to the vat.

E 4.2.4 *Mechanical agitators.* The mechanical agitators shall be of sanitary construction. The carriage and track shall be so constructed as to prevent the dropping of dirt or grease into the vat. Metal blades, forks, or stirrers shall be constructed of stainless steel and of material approved in the 3–A Sanitary Standards for Plastic and Rubber or Rubberlike Materials and shall be free from rough or sharp edges which might scratch the equipment or remove metal particles.

E 4.2.5 *Curd mill and miscellaneous equipment.* Knives, hand rakes, shovels, paddles, strainers, and miscellaneous equipment shall be stainless steel or of material approved in the 3–A Sanitary Standards for Plastic and Rubberlike Material. The product contact surfaces of the curd mill shall be of stainless steel. All pieces of equipment shall be so constructed that they can be kept clean. The wires in the curd knives shall be stainless steel, kept tight and replaced when necessary.

E 4.2.6 *Hoops and followers.* The hoops, forms, and followers shall be constructed of stainless steel or heavy tinned steel. If tinned, they shall be kept tinned and free from rust. All hoops, forms, and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

E 4.2.7 *Press.* The cheese press shall be constructed of stainless steel and all joints welded and all surfaces, seams, and openings readily cleanable. The pressure device shall be the continuous type. Press cloths shall be maintained in good repair and in a sanitary condition. Single-service press cloths shall be used only once.

E 4.2.8 *Rindless cheese press.* The press used to heat seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surface and have controls that shall provide uniform pressure and heat equally to all surfaces.

E 4.2.9 *Paraffin tanks.* The metal tank shall be adequate in size, have wood rather than metal racks to support the cheese, have heat controls and an indicating thermometer. The cheese wax shall be kept clean.

E 4.3 *Operations and operating procedures*—E 4.3.1 *Cheese from pasteurized milk.* (a) If the cheese is labeled as pasteurized, the milk shall be pasteurized by subjecting every particle of milk to a minimum temperature of 161° F. for not less than 15 seconds.

(b) HTST pasteurization units shall be equipped with the proper controls and equipment to assure pasteurization. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45° F. or lower until time of setting.

E 4.3.2 *Cheese from unpasteurized milk.* If the cheese is labeled as "heat treated," "unpasteurized," "raw milk," or "for manufacturing," the milk may be raw or heated at temperatures below pasteurization. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45° F. or lower until time of setting.

E 4.3.3 *Whey disposal.* (a) Adequate sanitary facilities shall be provided for the disposal of whey. If outside, necessary precautions shall be taken to minimize flies, insects, and development of objectionable odors.

(b) Whey or whey products intended for human food shall at all times be handled in a sanitary manner in accordance with the procedures of this subpart as specified for handling milk and dairy products.

E 4.3.4 *Packaging and repackaging.* Packaging rindless cheese or cutting and repackaging all styles of bulk cheese shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and the packaging material shall be practically free from mold and bacterial contamination.

E 4.3.5 *General identification.* Each bulk cheese shall be legibly marked with the name of the product, code or date of manufacture, vat number, officially designated code number or name and address of manufacturer. Each consumer sized container shall be plainly marked with the name and address of the manufacturer, packer, or distributor, net weight of the contents, name of product and such other information as may be required.

SEC. E 5. *Supplemental requirements for plants manufacturing and packaging cottage cheese*—E 5.1 *Rooms and compartments*—E 5.1.1 *Processing rooms.* (a) Processing operations with open cheese vats shall be separated from other rooms or areas. Excessive personnel traffic or other possible contaminating conditions shall be avoided. Rooms, compartments, cookers, and dry storage space in which any raw material, packaging or ingredient supplies or finished products are handled, processed, packaged, or stored shall be designed and constructed to assure clean and orderly operations.

(b) *Ventilation.* Processing and packaging rooms or compartments shall be ventilated to maintain sanitary conditions, preclude the growth of mold and airborne bacterial contaminants, prevent undue condensation of water vapor and minimize or eliminate objectionable odors. To minimize airborne contamination in processing and packaging rooms, it is preferable to filter all incoming air. The incoming air shall exert an outward pressure so that the movement of air will be outward and prevent the movement of unfiltered air inward.

E 5.1.2 *Starter room.* Starter rooms or areas shall be properly equipped and maintained for the propagation and

handling of starter cultures. All necessary precautions shall be taken to prevent contamination of the starter room, the equipment and the air therein.

E 5.1.3 *Coolers.* Coolers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the quality and condition of the products. Coolers shall be kept clean, orderly, free from insects, rodents, and mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

E 5.2 *Equipment and utensils*—E 5.2.1 *General construction, repair and installation.* The equipment and utensils used for the manufacture and handling of cottage cheese shall be as specified in section 1.4 of subpart E. In addition for certain other equipment the following requirements shall be met.

E 5.2.2 *Cheese vats.* (1) The vats used for making the cottage cheese shall be of stainless steel construction with adequate jacket capacity for uniform heating and cooling. The inner liner shall be minimum 16 gage stainless steel, or equally corrosion-resistant metal properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jacket shall be constructed as to prevent milk or cheese from entering the inner jacket.

(a) Vats shall be equipped with valves to control the heating and cooling medium and a suitable sanitary outlet valve. Also, the vats shall be equipped with removable stainless steel or other suitable metal covers, cloth covers which can be regularly and suitably laundered, or with single service paper covers. Vats used for creaming curd shall be equipped with a refrigerated cooling medium.

E 5.2.3 *Agitators.* Mechanical agitators shall be installed on all cheese vats for stirring the milk or cheese. The carriage shall be completely enclosed or provided with a trough or drip pan to prevent condensation, oil, or dirt from dropping into the vat.

E 5.2.4 *Container fillers.* New fillers shall conform to the 3–A Sanitary Standards for Equipment for Packaging Frozen Desserts and Cottage Cheese.

E 5.2.5 *Mixers.* They shall be constructed in such a manner as to be readily cleanable. If shafts extend through the wall of the tank below the level of product, they shall be equipped with proper seals which are readily removable for cleaning and sanitizing. The mixer shall be enclosed or equipped with tight fitting covers.

E 5.2.6 *Starter vats.* Bulk starter vats shall be made of stainless steel or equally corrosion resistant metal, shall be in good repair, equipped with tight fitting lids and accurate temperature controls such as valves, indicating and/or recording thermometers. New vats shall be constructed according to applicable 3–A Sanitary Standards.

E 5.3 *Operations and operating procedures*—E 5.3.1 *Pasteurization.* (a) The skim milk used for the manufacture of cottage cheese shall be pasteurized not more than 24 hours prior to the time of setting by heating every particle of skim milk to a temperature of 161° F. for not less than 15 seconds or by any other combination of temperature and time giving equivalent results. All skim milk must be cooled promptly to setting temperature. If held more than 2 hours between pasteurization and time of setting, the skim milk shall be cooled and held at 45° F. or colder until set.

(b) Cream or cheese dressing shall be pasteurized at not less than 150° F. for not less than 30 minutes or at not less than 166° F. for not less than 15 seconds or by any other combination of temperature and time treatment giving equivalent results. Cream and cheese dressing shall be cooled promptly to 40° F. or lower after pasteurization to aid in further cooling of cottage cheese curd for improved keeping quality.

(c) Reconstituted nonfat dry milk for cottage cheese manufacture need not be repasteurized provided it is reconstituted within 2 hours prior to the time of setting. Skim milk separated from pasteurized whole milk need not be repasteurized provided it is separated in equipment from which all traces of raw milk from previous operations have been removed by proper cleaning and sanitizing.

E 5.3.2 *Reconstituting nonfat dry milk.* Nonfat dry milk shall be reconstituted in a sanitary manner, preferably by the use of a centrifugal pump and funnel arrangement. It shall be reconstituted within 2 hours of the time of setting, using water which is free from viable pathogenic or otherwise harmful microorganisms.

E 5.3.3 *Packaging and general identification*—(a) *Containers.* Containers used for packaging cottage cheese shall be any commercially acceptable multiple use or single service container or packaging material which will satisfactorily protect the contents through the regular channels of trade without significant impairment of quality with respect to flavor or contamination under normal conditions of handling. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing 2 pounds or less to protect the product from contamination during subsequent handling.

(b) *Packaging.* The cheese shall be packaged in a sanitary manner. The containers shall be check weighed during the filling operation to assure they are filled uniformly to not less than the stated net weight on the container.

(c) *General identification.* Bulk packages containing cottage cheese shall be adequately and legibly marked with the name of the product, net weight, name and address of the manufacturer, lot number, code or date of packaging and any other identification as may be required. Consumer size packaged products shall be legibly marked with the name of the product, net weight, name and address of the manufacturer or distributor, code or date of packaging and any other identification as may be required.

E 5.3.4 *Storage of finished product.* Cottage cheese after packaging shall be promptly stored at a temperature of 45° F. or lower to maintain quality and condition until loaded for distribution. During distribution and storage prior to sale the product should be maintained at a temperature of 45° F. or lower. The product shall not be exposed to foreign odors or conditions such as drippage or condensation that might cause package or product damage. Packaged cottage cheese shall not be placed directly on floors.

SEC. E 6. *Supplemental requirements for plants manufacturing, processing and packaging pasteurized process cheese and related products*—E 6.1 *Equipment and utensils*—E 6.1.1 *General construction, repair, and installation.* The equipment and utensils used for the handling and processing of cheese products shall be as specified in section 1.4 of subpart E. In addition, for certain other equipment the following requirements shall be met.

E 6.1.2 *Conveyors.* Conveyors shall be constructed of material which can be properly cleaned, will not rust, or otherwise contaminate the cheese, and shall be maintained in good repair.

E 6.1.3 *Grinders or shredders.* The grinders or shredders used in the preparation of the trimmed and cleaned natural cheese for the cookers shall be adequate in size. Product contact surfaces shall be of corrosion resistant material, and of such construction as to prevent contamination of the cheese and to allow thorough cleaning of all parts and product contact surfaces.

E 6.1.4 *Cookers.* The cookers shall be the steam jacketed or direct steam type. They shall be constructed of stainless steel or other equally corrosion-resistant material. All product contact surfaces shall be readily accessible for cleaning. Each cooker shall be equipped with an indicating thermometer, and should be equipped with a temperature recording device. The recording thermometer stem may be placed in the cooker if satisfactory time charts are used; if not, the stem shall be placed in the hotwell or filler hopper. Steam check valves on direct steam type cookers shall be mounted flush with cooker wall, be constructed of stainless steel and designed to prevent the backup of product into the steam

line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily cleaned. If direct steam is applied to the product only culinary steam shall be used.

E 6.1.5 *Fillers.* The hoppers of all fillers shall be covered but the cover may have sight ports. If necesary, the hopper may have an agitator to prevent buildup on side wall. The filler valves and head shall be kept in good repair, capable of accurate measurements.

E 6.2 *Operations and operating procedures*—E 6.2.1 *Trimming and cleaning.* The natural cheese shall be cleaned free of all nonedible portions. Paraffin and bandages as well as rind surface, mold, or unclean areas or any other part which is unwholesome or unappetizing shall be removed.

E 6.2.2 *Cooking the batch.* Each batch of cheese within the cooker, including the optional ingredients shall be thoroughly commingled and the contents pasteurized at a temperature of at least 158° F. and held at that temperature for not less than 30 seconds. Care shall be taken to prevent the entrance of cheese particles or ingredients after the cooker batch of cheese has reached the final heating temperature. After holding for the required period of time, the hot cheese shall be emptied from the cooker as quickly as possible.

E 6.2.3 *Forming containers.* Containers either lined or unlined shall be assembled and stored in a sanitary manner to prevent contamination. The handling of containers by filler crews shall be done with extreme care and observance of personal cleanliness. Preforming and assembling of pouch liners and containers shall be kept to a minimum and the supply rotated to limit the length of time exposed to possible contamination prior to filling.

E 6.2.4 *Filling containers.* Hot fluid cheese from the cookers may be held in hot wells or hoppers to assure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount of product into the pouch or containers in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening. An effective system shall be used to maintain accurate and precise weight control. Damaged or unsatisfactory packages shall be removed from production, and the cheese may be salvaged into sanitary containers, and added back to cookers.

E 6.2.5 *Closing and sealing containers.* Pouches, liners, or containers having product contact surfaces after filling shall be folded or closed and sealed in a sanitary manner, preferably by mechanical means, so as to assure against contamination. Each container in addition to other required labeling shall be coded in such a manner as to be easily identified as to date of manufacture by lot or sublot number.

SEC. E 7. *Supplemental requirements for plants manufacturing, processing, and packaging evaporated, condensed, or sterilized milk products*—E 7.1 *Equipment and utensils*—E 7.1.1 *General construction, repair, and installation.* The equipment and utensils used for processing and packaging evaporated, condensed, or sterilized milk products shall be as specified in section 1.4 of Subpart E. In addition, for certain other equipment, the following requirements shall be met.

E 7.1.2 *Evaporators and vacuum pans.* All equipment used in the removal of moisture from milk or milk products for the purpose of concentrating the solids should meet the requirements of the 3–A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans. All new or used replacements for this type of equipment shall meet the appropriate 3–A Sanitary Standards.

E 7.1.3 *Fillers.* Both gravity- and vacuum-type fillers shall be of sanitary design and all product contact surfaces, if metal, shall be made of stainless steel or equally corrosion-resistant material; except that certain evaporated milk fillers having brass parts may be approved if free from corroded surfaces and kept in good repair. Nonmetallic product contact surfaces shall meet the requirements for 3–A Sanitary Standards for Rubber and Rubberlike Materials or for Multiple-Use Plastic Materials. Fillers shall be designed so that they in no way will contaminate or detract from the quality of the product being packaged.

E 7.1.4 *Batch or continuous in-container sterilizers.* Shall be equipped with accurate temperature controls and effective valves for regulating the sterilization process. The equipment shall be maintained in such a manner as to assure control of the length of time of processing, and to minimize the number of damaged containers.

E 7.1.5 *Homogenizers.* Homogenizers where applicable shall be used to reduce the size of the fat particles and to evenly disperse them in the product. New homogenizers shall meet the applicable 3–A Sanitary Standards.

E 7.2 *Operations and operating procedures*—E 7.2.1 *Preheat, pasteurization.* When pasteurization is intended or required by either the vat method, HTST method, or by the UHT method it shall be accomplished by systems and equipment meeting the requirements outlined in section 1.4 of Subpart E.

E 7.2.2 *Sterilization.* The complete destruction of all living organisms shall be performed in one of the following methods: (a) The complete in-container method, by heating the container and contents to a range of 212° F. to 280° F. for a sufficient time; (b) by a continuous flow UHTST process at high temperatures of 280° F. and above for a sufficient time, then packaged aseptically; (c) the product is first sterilized according to UHTST methods as in paragraph (b) of this section, then packaged and given further heat treatment to complete the sterilization process.

E 7.2.3 *Filling containers.* (a) The filling of small containers with product shall be done in a sanitary manner. The containers shall not contaminate or detract from the quality of the product in any way. After filling, the container shall be hermetically sealed.

(b) Bulk containers for unsterilized product shall be suitable and adequate to protect the product in storage or transit. The bulk container (including bulk tankers) shall be cleaned and sanitized before filling, and filled and closed in a sanitary manner.

E 7.2.4 *Aseptic filling.* A previously sterilized product shall be filled under conditions which prevent contamination of the product by living organisms or spores. The containers prior to being filled shall be sterilized and maintained in a sterile condition. The containers shall be sealed in a manner that prevents contamination of the product.

E 7.2.5 *Storage.* Proper facilities shall be provided for the storage and handling of finished product.

Subpart F—Administrative Procedures

SEC. F 1. *Farm certification*—F 1.1 *Necessity for certification.* (a) Within 24 months from the effective date of these rules and regulations, every farm producing and selling milk for manufacturing purposes shall be inspected and certified as provided in section F 1.2, 1.3, and 1.5. On and after the effective date of these rules and regulations, a new producer's farm shall be inspected and certified as provided in sections F 1.2, 1.3, and 1.5 before his first sale of milk for manufacturing purposes. Twenty-four months from and after the effective date of these rules and regulations, no milk for manufacturing purposes produced on an uncertified farm shall be bought or sold.

(b) Certified farms shall be inspected annually after initial certification to determine eligibility for recertification. The inspection procedure for recertification shall be the same as that for initial certification.

F 1.2 *Inspection.* Each farm shall be inspected by an inspector or approved fieldman. When evidence indicates that it is advisable to do so [the regulatory agency] may require an examination of the herd by a licensed veterinarian. If the farm meets the applicable requirements for certification described in section D 1 to D 9 of subpart D, as indicated by the Farm Certification Report Form (section F 4) the farm shall be certified as described in section F 1.3. If the farm does not meet the requirements for certification, it shall be reinspected

within 30 days after the initial inspection. If the farm then meets the requirements for certification, it shall be certified. If the farm does not meet the requirements for certification, it shall not be certified, and the producer's authorization to sell milk for human food from that farm shall be withheld by [the regulatory agency] until such time as the farm qualifies for certification. Provided that, if the inspector determines during any of these inspections that corrections on the farm will require some capital investment, a reasonable extension of the prescribed time limits may be granted by [the regulatory agency]. Each completed Farm Certification Report Form (section F 4) shall be kept by the regulatory agency and a copy shall be given to the producer.

F 1.3 *Certification.* An inspector or approved fieldman shall certify farms that meet the requirements of sections D 1 to D 9 of subpart D as applicable, based upon the inspection procedure described in section F 1.2. Farm certification shall authorize the sale from that farm of milk for manufacturing purposes that meets the quality standards of section C 2 to C 4 of subpart C as determined by the procedures described in sections C 2 to C 11 of subpart C.

F 1.4 *Expiration and revocation of certification.* (a) Farm certification shall expire and become renewable 1 year from the date of certification unless revoked earlier by [the regulatory agency] and no certification shall be transferrable.

(b) If at any time an inspector or approved fieldman determines that a certified farm does not meet the requirements for certification [the regulatory agency] may allow a reasonable probationary period for the producer to bring his farm within the requirements for certification. If at the end of this time the farm does not meet the requirements for certification [the regulatory agency] may revoke the farm certification.

F 1.5 *Reinstatement.* If, after a period of withholding, probation, or revocation of farm certification, a producer makes the necessary corrections at the farm, he may apply for reinspection. When conditions have been corrected, the farm shall be reinspected by an inspector or approved fieldman. When the inspector or approved fieldman determines that requirements for certification have been met, he shall certify the farm.

SEC. F 2. *Licensing plants, milk graders, and bulk milk collectors*—F 2.1 *Necessity for plant license.* (a) Within 12 months from the effective date of these rules and regulations, every plant receiving or processing milk for the manufacture of dairy products shall be inspected and licensed as provided in sections F 2.2, 2.3, 2.4(a), and 2.6. On and after the effective date of these rules and regulations, a new plant shall be inspected and licensed as provided in sections F 2.2, 2.3, 2.4(a), and 2.6 before buying or processing any milk for the manufacture of dairy products. Twelve months from and after the effective date of these rules and regulations, no unlicensed plant shall handle, purchase, or receive milk or manufacture dairy products therefrom.

(b) All licensed plants shall be inspected annually after issuance of the initial license to determine eligibility for license renewal. The inspection procedure for license renewal shall be the same as that for initial licensing.

F 2.2 *Application for license.* Applications to [the regulatory agency] for a new or renewal license for dairy plants, milk graders, and bulk milk collectors shall contain the name and address of the applicant and such other pertinent information as may be required.

F 2.3 *Plant inspection.* (a) Each plant shall be inspected by an inspector. If, upon initial inspection, the inspector finds that the plant meets the requirements for licensing described in subpart E, as indicated by the Plant Inspection Report Form (section F 5), a license shall be issued to the plant as described in section F 2.4(a). If the plant does not meet the requirements for licensing, the plant shall be reinspected by an inspector within 30 days of the initial inspection. A longer time may be allowed if major changes or new equipment is required. If at this time the plant meets the requirements for licensing, a license shall be issued. If the plant does not meet the requirements for licensing, it shall not be licensed, and its authorization to handle, purchase, or receive milk or to manufacture dairy products therefrom shall be withheld until such time as the plant qualifies for a license.

(b) Each completed Plant Inspection Report Form (section F 5) shall be kept by [the regulatory agency], and a copy shall be given to the plant operator.

F 2.4 *Issuance of license*—(a) *Dairy plants.* [The regulatory agency] shall license dairy plants that meet the specifications of subpart E based upon the inspection procedure described in section F 2.3. The license certificate shall be posted conspicuously at the plant. The license shall authorize the plant to test, purchase, and receive milk for manufacturing purposes and to manufacture dairy products therefrom, in compliance with the applicable provisions of the Act and the rules and regulations issued pursuant thereto.

(b) *Milk graders and bulk milk collectors.* [The regulatory agency] shall license milk graders and bulk milk collectors who meet the qualifications prescribed by [the regulatory agency]. The licenses of milk graders and bulk milk collectors shall authorize them to grade, accept, and reject raw milk in accordance with the provisions of subpart C.

F 2.5 *Expiration, suspension and revocation of license.* (a) Licenses shall expire and become renewable 1 year from the date of issuance unless revoked earlier and no license shall be transferable.

(b) If at any time an inspector determines that a licensed plant does not meet the requirements for licensing, he may allow a reasonable probationary period for the operator to bring his plant within the requirements for licensing. If at the end of this time the plant does not meet the licensing requirements [the regulatory agency] may revoke the plant license.

(c) [The regulatory agency] may suspend or revoke licenses of milk graders and bulk milk collectors for any violation of these regulations on the Act. An opportunity for a hearing shall be provided any licensee before suspension or revocation of his license.

F 2.6 *Reinstatment.* (a) If, after a period of withholding, probation or revocation of a plant license, the operator makes the necessary corrections at the plant, he may apply to [the regulatory agency] for reinspection and reinstatement. When the inspector determines that requirements for licensing have been met [the regulatory agency] shall issue a license to the plant.

(b) The reinstatement of licenses for milk graders and bulk milk collectors which have been suspended or revoked shall be made only after satisfying [the regulatory agency] of their qualifications.

Sec. F 3. *Supervision*—F 3.1 *Regulatory agency.* [The regulatory agency] to insure compliance with the provisions of the Act and the rules and regulations shall:

(a) Make periodic examinations of milk from a representative number of producers at each plant to determine whether the milk is being graded and tested in accordance with the applicable provisions of subpart C.

(b) Examine the quality records of transfer producers at each plant periodically and when necessary determine the acceptability of such producers' milk.

(c) Make periodic farm inspections and compare the results of such inspections with previously completed Farm Certification Report Forms filed by the inspector or approved fieldman.

(d) Periodically examine the milk quality tests records of individual producers at each plant.

(e) Periodically inspect plant premises, buildings, equipment, facilities, operations, sanitary practices and compare the results with previously completed plant inspection forms filed by the inspector.

(f) Assist plant management and laboratory and field staffs with educational programs among producers relating to quality improvement of milk.

(g) Perform such other services and institute such other supervisory procedures as may be necessary to insure compliance with the provisions of the Act and the rules and regulations.

F 4. *Farm certification report form.* The following form shall be used by inspectors or approved fieldman in determining eligibility for farm certification:

FARM INSPECTION FORM

	Check one		Remarks (State unsatisfactory conditions by Item No. Include comments, as necessary, for other items)
	S	U	
A—FACILITIES			
1. Health of herd:			
(a) Herd appears healthy			
(b) Tuberculin tested, date _____			
(c) Brucellosis tested:			
Ring tested, date _____			
Blood tested, date _____			
2. Barn or milking area:			
(a) Adequate size, construction			
(b) Cow yard graded, well drained			
(c) Bulk tank, installation			
3. Milkhouse or milkroom:			
(a) Adequate size, location, and construction			
(b) Equipped with adequate facilities			
(c) Bulk tank, installation			
4. Combination milking parlor and milkroom, if used:			
(a) Adequate size, construction			
(b) Equipment and arrangement			
5. Utensils and equipment:			
(a) Design, construction			
(b) Cleaning (brushes and cleansers) and storage facilities and supplies available			
6. Water supply:			
(a) Safe, clean			
(b) Supply ample			
B—METHODS			
7. Premises:			
(a) Clean, well kept			
(b) Fowl, swine properly confined			
(c) Manure properly handled and disposed of			
8. Barn or milking area:			
(a) Floors and gutters clean, good repair			
(b) Walls and ceilings clean, painted or whitewashed			
(c) Pens and alleyways clean			
(d) Yard or loating area clean			
9. Milking procedure:			
(a) Mastitis program practiced			
(b) Cows clean, udders and flanks clipped			
(c) Udders and teats washed or wiped before milking			
(d) Milk stools and surcingles clean, properly stored			
(e) Milker's clothing clean, hands clean and dry			
(f) Feed bin kept clean and free from foul odors			
10. Milkhouse or milkroom:			
(a) Used for handling milk and utensil care only			
(b) Clean, flies and insects controlled to minimum			
11. Cooling:			
(a) Facilty clean, good operating order			
(b) Milk cooled promptly, properly held. (Temperature of milk —° F.)			

FARM INSPECTION FORM—Continued

	Check one		Remarks (State unsatisfactory conditions by Item No. Include comments, as necessary, for other items)
	S	U	
A—FACILITIES			
12. Utensils and equipment:			
(a) Good condition, clean, properly stored:			
Cans			
Milking machines (head, claw, pulsator, inflations, tubes, air hose, etc.)			
Pails, strainers and other utensils			
(b) Bactericidal treatment before use			
(c) Vacuum lines clean			
(d) Supplies properly stored			

F 5. *Plant inspection report form.* **The following form shall be used by inspectors in determining eligibility for plant licensing:**

PLANT SURVEY REPORT

	Type of plant	Date
	Manager	_____
Plant surveyed (*Name and address*)	Purpose of survey	_____
		_____
		Inspector

Item ↓ Code: S—Satisfactory → U—Unsatisfactory	Check one S	Check one U	Remarks (*State unsatisfactory conditions by Item No. Include comments, as necessary, for other items.*)
Plant and premises:			
1 Plant driveway and surroundings.			
2 Construction			
3 Floor Drains			
4			
5			
Receiving—Cans:			
6 Room construction			
7 Lighting and ventilation			
8 Can inlet and outlet			
9 Weight tank, scale, and drop tank.			
10 Can washer			
11 Disposition of can drippings			
12 Condition of producer cans			
13 Pumps, pipelines, fittings			
14 Milk route trucks			
15			
16			

PLANT SURVEY REPORT—Continued

Item ↓ Code: S—Satisfactory U—Unsatisfactory →	Check one S	Check one U	Remarks (State unsatisfactory conditions by Item No. Include comments, as necessary, for other items.)
Receiving—bulk:			
17 Facilities for bulk trucks			
18 Bulk tank trucks			
19 Pumps, pipelines, fittings			
20 CIP cleaning			
21			
22			
23			
Quality program—Raw product:			
24 Line grading			
25 Bacterial testing			
26 Sediment testing			
27 Quality—supply plants			
28 Quality records—Follow-up			
29 Field service			
30			
31			
Raw milk storage			
32 Room Construction			
33 Lighting and ventilation			
34 Product coolers			
35 Storage tanks—silo			
36 Storage tanks—conventional			
37 Pumps, pipelines, valves			
38 CIP cleaning			
39			
40			

BUTTER

Item ↓ Code: S—Satisfactory U—Unsatisfactory →	Check one S	Check one U	Remarks (State unsatisfactory conditions by Item No. Include comments, as necessary, for other items.)
Processing:			
B41 Room construction			
B42 Lighting and ventilation			
B43 Forewarmer			
B44 Neutral method—Cream filter			
B45 Separator(s)			
B46 Pasteurization			
B47 Thermometer—Indicating and recording			
B48 Vacuumizer			
B49 Product cooler			
B50 Storage tanks			
B51 Pumps, pipelines, valves			
B52 CIP cleaning			
B53			
B54			
B55			
Churning:			
B56 Room construction			
B57 Lighting and ventilation			
B58 Cream filter			
B59 Churn(s)			
B60 Disposition of buttermilk			
B61 Butter wash water, add water			
B62 Wash water tank, filter			
B63 Pumps, pipelines, fittings			
B64 Starter—distillate			
B65 Butter boats, trucks, packers			
B66 Scales (bulk butter)			
B67 Miscellaneous utensils			
B68 Hand washing facilities			
B69			
B70			
B71			
Composition control:			
B72 Equipment—scales, weights, cups			
B73 Tests performed			
B74 Technique			
B75			
B76			
Packaging of product:			
B77 Liners and treatment			
B78 Package finish			
B79 Type of containers			
B80 Markings			
B81			
Storage of finished product:			
B82 Floor, walls, ceiling, doors			
B83 Lighting and ventilation			
B84 Temperature of room			
B85 Pallets or floor racks			
B86 Stacking of boxes			
B87 Other products stored			
B88			
B89			

CHEESE

Item ↓ Code: S–Satisfactory U–Unsatisfactory →	Check one S	Check one U	Remarks (*State unsatisfactory conditions by Item No. Include comments, as necessary, for other items.*)
Processing:			
C41 Room construction			
C42 Lighting and ventilation			
C43 Clarifier, separator			
C44 Pasteurization			
C45 Thermometer—Indicating and recording			
C46 Vacuumizer			
C47 Pumps, valves, fittings			
C48 CIP cleaning			
C49			
C50			
Starter room:			
C51 Room construction			
C52 Lighting and ventilation			
C53 Processing vats			
C54 Starter cans			
C55 Starter culture			
C56			
Cheesemaking room:			
C57 Room construction			
C58 Lighting and ventilation			
C59 Vats, agitators and drain tables			
C60 Cheese hoops and presses			
C61 Press cloths			
C62 Curd knives and mill			
C63 Forks, rakes, and miscellaneous utensils			
C64 Salt bin			
C65 Hand washing facilities			
C66 Housekeeping			
C67			
Packaging:			
C68 Room construction			
C69 Lighting and ventilation			
C70 Wrapper table and scale			
C71 Type of wrapper—sealing			
C72 Barrels—condition			
C73 Markings			
C74 Housekeeping			
C75			
C76			
Storage of finished product:			
C77 Room construction			
C78 Temperature and ventilation			
C79 Drying room, shelves, carts			
C80 Pallets or floor racks			
C81			
C82			
Handling of whey:			
C83 Holding tank—unseparated whey			
C84 Separator			
C85 Pumps, pipelines, fittings			
C86 Whey cream—pasteurized and cooling			
C87 Disposition of press drippings			
C88 Storage area—separated whey			
C89 Disposition of whey			

DRY MILK

Item ↓ Code: S—Satisfactory U—Unsatisfactory →	Check one S	Check one U	Remarks (*State unsatisfactory conditions by Item No. Include comments, as necessary, for other items.*)
Pasteurization and condensing:			
41 Floors, walls, ceiling, windows, doors			
42 Lighting and ventilation			
43 Storage tanks—temperature			
44 Preheaters			
45 HTST pasteurization-holding tube, time, temperature.			
46 Positive pump or timing device			
47 Flow diversion valve-divert temperature			
48 Recorder-controller			
49 Indicating and recording thermometer			
50 Hotwell			
51 Evaporator(s)			
52 Product cooler (condensed milk)			
53 Condensed surge tank			
54 Pumps, pipelines, valves, and fittings			
55 CIP cleaning			
56			
Drying:			
57 Floors, walls, ceiling, windows, doors			
58 Lighting and ventilation			
59 Condensed milk preheater			
60 H.P. pump and strainers			
61 Pumps, pipelines, valves, and fittings			
62 Air supply, filters, inlet chamber			
63 Drying chamber—make of dryer, redryer			
64 Prod. removal and conveying equipment			
65 Collectors			
66 Powder cooling system			
67 Storage bins			
68 Shoe covers, miscellaneous (for dryer work)			
69 Vacuum cleaner			
70 Housekeeping and pest control			
71			
72			
73			
Packaging:			
74 Floors, walls, ceiling, windows, doors			
75 Lighting			
76 Room exhaust, ventilation			
77 Sifter			
78 Dry milk packaging temperature			
79 Scale			
80 Packaging technique			
81 Waste powder-disposition			
82 Housekeeping and pest control			
83			
Storage of dry milk:			
84 Floors, walls, ceiling, windows, doors			
85 Lighting and ventilation			
86 Stacking of containers			
87 Other products stored			
88 Housekeeping and pest control			
89			
90			

Form C EVAPORATED, CONDENSED OR STERILE MILK PRODUCTS

Item ↓ Code: S—Satisfactory → U—Unsatisfactory	Check one S	Check one U	Remarks (State unsatisfactory conditions by Item No. include comments, as necessary, for other items.)
Pasteurization and condensing:			
41 Floors, walls, ceiling, windows, doors			
42 Lighting and ventilation			
43 Storage tanks—temperature			
44 Preheaters			
45 Heat treatment—temperature time			
46 Hot well			
47 Indicating and recording thermometer			
48 Carrageenan equipment			
49 Evaporator(s)			
50 Filters			
51 Homogenizer			
52 Product cooler			
53 Storage or standardizing tank—temperature			
54 Pumps, pipelines, valves, and fittings			
55 CIP cleaning			
56			
57			
58			
Filling and sterilizing:			
59 Floors, walls, ceiling, windows, doors			
60 Lighting and ventilation			
61 Surge tank to fillers			
62 Filler condition			
63 Filler parts storage			
64 Pumps, pipelines, valves, and fittings			
65 Preheater—temperature-time			
66 Sterilizer—temperature-time			
67 Cooler—temperature			
68 Indicating and recording thermometer			
69 Pellet and/or leak detector			
70 Can dryer			
71 Can bin storage			
72 Housekeeping and pest control			
73			
74			
75			
Labeling and coding:			
76 Floors, walls, ceiling, windows, doors			
77 Lighting and ventilation			
78 Labeling equipment			
79 Coding—can and case			
80 Casing equipment			
81 Label storage			
82 Housekeeping and pest control			
83			
Storage of product:			
84 Floors, walls, ceiling, windows, doors			
85 Lighting and ventilation			
86 Stacking of containers			
87 Other products stored			
88 Housekeeping and pest control			
89			
Laboratory:			
90 Facilities and equipment			
91 Lighting and ventilation			
92 Quality control—manufacturing products			
Storage of supplies:			
93 Room construction			
94 Salt, color, starter, rennet, etc			
95 Containers, liners, wrappers			
96 Other supplies			
97 Housekeeping			
98 Pest control			
99			
Lockers and restrooms:			
100 Location			
101 Room construction			
102 Lighting and ventilation			
103 Lockers and benches			
104 Housekeeping			
105 Handwashing facilities and sign			
106			
General:			
107 Pest control program			
108 Medical certificate			
109 Employees' appearance and habits			
110 Boiler and compressor room			
111 Water—plant supply			
112			

Status of plant—Previous survey, if any | Date

Status of plant—This survey (*Indicate product(s)*)

Recommendations:

Done at Washington, D.C., this 28th day of March 1972.

G. R. GRANGE,
Acting Administrator.

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